CDC Responses to External Peer Reviewers' Comments on the Draft Recommendations for HIV Prevention with Adults and Adolescents with HIV in the United States

Notes: The bulk of reviewers' comments were provided in the form of track changes or in marginal comment fields in the draft document. Many comments were telegraphic in style and would be difficult to interpret out of context. For this reason, all passages to which reviewers referred were excerpted and most reviewers' comments were paraphrased. For brevity, citation numbers within excerpted passages were omitted (but are available on request).

In the **Reviewers Comment,** page numbers and numeric superscripts refer to the page number and citation numbers in the draft reviewers read during September-November 2013.

In the **Workgroup's Response,** the page numbers and citation numbers in the revised draft sent to HHS in September 2014.

General Comments

Comments from Del Rio

1. **Comment:** The boxed recommendations are quite long and most are so obvious, e.g., "Do not engage in discrimination....."
   Response: Many of boxed recommendations have been trimmed and reformatted with useful headers to make them easier to digest. Some "overarching" recommendations that describe contextual factors, e.g., avoiding discrimination and ensuring confidentiality, were advocated by guideline stakeholders, including persons with HIV and HIV advocacy and legal organizations. In some cases, overarching recommendations in Section 4 (Context) are reiterated in relevant chapters (e.g., both Context and Partner Services section address confidentiality) because many stakeholders wanted each section to "stand alone."

2. **Comment**: The reviewer notes that the topics on "Limitations and Risks of the Recommendations" are not useful and may only include background information.
   Response: IOM and CDC guideline content standards advise that all guidelines include discussion of limitations and risks of the recommendations that addresses underutilization of the recommendations and challenges for implementation. To address request by this and other reviewers to frame these issues in more positive way, this topic was renamed "Implementation progress, challenges and opportunities," but contains similar content.

Title Page

Comments from Del Rio

1. **Comment**: P 1. The reviewer questions the title, "Recommendations for HIV Prevention **with** Adults....." and asks by "for" is not used.

Response: P. 1: In response to input from stakeholders at the April 2011 consultation and during review of subsequent drafts, the workgroup chose "with" instead of "for" to underscore collaboration between persons with HIV and their providers.

Section – Abbreviations

Comments from Walensky

1. **Comment**: Suggested using the abbreviation DHHS.
   Response: CDC editors advise using HHS as per CDC Style Guide.

Section - Summary

Comments from Baker

1. **Comment**: P. 14. The bullet reading "Providing persons with HIV who are of reproductive age services for family planning, preconception counseling, and pregnancy care according to the latest DHHS recommandations" should be separated from STD area.
   Response: P. 16. In original and revised versions, the STD issue is noted separately.

2. **Comment:** P. 14. Regarding the passage, "Informing persons with HIV that some of their HIV-uninfected partners may be eligible to use non-occupational post-exposure prophylaxis and pre-exposure prophylaxis to prevent HIV acquisition," the reviewer asks why only some partners of HIV positive person why would be eligible for nPEP and adds that this may contribute to ongoing false perceptions of risk.
   Response: P. 16. This was revised as "Informing persons with HIV about the availability of preexposure prophylaxis (PrEP) or nonoccupational postexposure prophylaxis (nPEP) for HIV-uninfected partners when clinically indicated to reduce their risk of HIV acquisition." This clarifies that eligibility for prophylaxis is determined by the prescribing clinician and relates to specific clinical indications for PrEP (for persons with substantial risk of HIV) and for nPEP (nPEP only indicated for persons exposed in past 72 hours).

Comments from Thrun

1. **Comment**: P. 12. Reviewer asks if this section can underscore that personal health is public/community health; that lowering viral load, across enough patients, can make a community level difference; and that adherence counseling, across the right patient population, matters at the population level. He adds that by stressing public health, providers will recognize that individual patient care contributes to community well-being.
   Response: P. 12. The revision addresses the issue of using treatment as an individual and public health intervention more directly: "By applying this expanded set of interventions, health care providers, nonclinical HIV prevention specialists, and health departments can promote the health of persons with HIV, prevent HIV transmission to their sex and drug-injection partners and offspring, and contribute to community well-being."

Section 1 - Introduction

Comments from Walensky

1. **Comment**: P. 16. This passage has redundant elements. "Moreover, only about 45% of persons receiving outpatient HIV medical care reported receiving prevention counseling from a physician, nurse, or other health-care provider during the preceding year. While most adults with HIV who are aware of their infection modify sexual behaviors and reduce the frequency of needle-sharing that might transmit HIV, many do not maintain these changes over time. Persons at a young age with diagnosed HIV may find it challenging to sustain safe behavior over the many decades after their diagnosis. (Furthermore, only a minority of persons with HIV receive HIV prevention counseling from physicians because of time constraints, competing clinical priorities, uncertainty that counseling will motivate behavior change, and other factors.)"
   Response: P. 20. The passage was reorganized and updated with new citations to address provider risk assessment and safer behaviors: "Nationally representative data also indicate that only about 45% of persons receiving outpatient HIV medical care reported receiving HIV prevention counseling from a health care provider during the preceding year. This may be due to time constraints, competing clinical priorities, lack of training or knowledge about sexual health and injection-drug use, uncertainty that counseling will motivate behavior change, and other factors. Many persons with HIV do not receive routine screening for sexually transmitted diseases (STDs) that may facilitate HIV transmission or services to notify partners of possible HIV exposure. Personal choice to defer safer behaviors also contributes to HIV transmission. Studies conducted in the United States when ART was routinely initiated at CD4 cell counts below 350 show that many adolescents and adults with HIV who are aware of their infection status did not practice safe sex and drug-injection behaviors. In 2011, an estimated 13% of MSM with HIV reported engaging in sex without a condom with male partners who were HIV-uninfected or whose infection status was unknown."

2. **Comment**: P. 17. In this passage, the acronym MSM was previously defined: "A meta-analysis that included several U.S. studies estimated 26% of men with HIV who have sex with men MSM) - report recent unprotected sex with partners who are either HIV-uninfected or have unknown infection status."
   Response: P. 20-21. This passage was updated with new data that specifies infection status of partners: "In 2011, an estimated 13% of MSM with HIV reported engaging in sex without a condom with male partners who were HIV-uninfected or whose infection status was unknown." Each acronym is spelled out the first time it is used in a section.

3. **Comment**: P. 17; Where it says "DRAFT" here, there are dark blocks on the actual printed page. The background is distracting as I read. Please make sure to remove on final draft.
   Response: This issue relates to reviewer's software. Finale version will exclude draft sign.

4. **Comment**: P. 19; In the passage noting that clinical providers, nonclinical providers, and staff of health departments and HIV planning groups are the intended audience for the report, the reviewer asks why patients with HIV are not listed as an audience for this report.

Response: P. 24. The passage was revised to clarify that patients with HIV are a secondary audience: "Secondary audiences for this report include persons with HIV, specialists in HIV/AIDS policy and law, funding, and service coverage and reimbursement for public and private sector health systems and community-based programs."

Comments from Baker

1. **Comment**: P. 16. Regarding the passage, "The number of newly infected persons exceeds the number of deaths among HIV-infected persons, which results in a net increase of about 30,000 persons with HIV each year," the reviewer notes this framework for presenting infections may be confusing and suggests more emphasis on populations and geographic areas where infections are occurring.
   Response: P. 19. This passage was revised and updated with new citations about the annual increase in the number of persons with HIV who might benefit from prevention and care interventions, and information on disparities by population and geography: "More than 1 million people are living with HIV in the United States, an increase of 60% over the previous 15 years. The number of newly infected persons exceeds the number of deaths among HIV-infected persons, which results in a net increase of about 30,000 persons with HIV each year. In 2011, about 60% of infections in adults and adolescents were diagnosed among gay, bisexual, and other men who have sex with men (MSM), nearly 30% in heterosexual women or men; and about 10% in persons who inject drugs. Persons diagnosed with HIV are disproportionately black/African-American and Hispanic/Latino and residents of selected states of the Southeast and Mid-Atlantic regions, Puerto Rico, the U.S. Virgin Islands, and about a dozen of the largest U.S. cities."

2. **Comment:** P. 16. Regarding the passage, "Currently, national data indicate that only a minority of persons with HIV benefit from biomedical and behavioral interventions that reduce their infectiousness and risk of exposing others to HIV," the reviewer notes that the statement lacks supporting evidence and implies that only a minority of people with HIV are practicing prevention. He adds that this phrasing suggest that people with HIV aren't in a position to benefit from these interventions.
   Response: P. 19. This passage was rephrased and bolstered by recent citations to stress that many persons do not benefit from the full range of interventions: **"**Most persons with HIV have taken steps to reduce the risk of transmitting HIV. Some may have started HIV care shortly after diagnosis, used ART to reduce infectiousness, or undergone STD screening and treatment. Others may have adopted safer sexual and drug-use behaviors, notified partners of possible HIV exposure, or used reproductive health services, substance use treatment, and other medical or social services that can lower transmission risk. Nevertheless, national data indicate that many persons with HIV do not benefit from the full range of biomedical, behavioral, and structural interventions that can reduce infectiousness and the risk of exposing others to HIV."

3. **Comment**: P. 16. Regarding the passage, "…only a minority of persons with HIV receive HIV prevention counseling from physicians because of time constraints, competing clinical priorities, uncertainty that counseling will motivate behavior change, and other factors," the reviewer notes this may be due to lack of provider training in sexual health.

Response: P. 20. This passage was revised to address provider training: "Nationally representative data also indicate that only about 45% of persons receiving outpatient HIV medical care reported receiving HIV prevention counseling from a health care provider during the preceding year. This may be due to time constraints, competing clinical priorities, lack of training or knowledge about sexual health and injection-drug use, uncertainty that counseling will motivate behavior change, and other factors. Many persons with HIV do not receive routine screening for sexually transmitted diseases (STDs) that may facilitate HIV transmission or services to notify partners of possible HIV exposure."

4. **Comment**: P. 17. Regarding the passage, "…54% of men who have sex with men (MSM), 42% of heterosexual women, and 32% of heterosexual men reported unprotected vaginal or anal sex in the past 12 months (confidence intervals for percentages not reported)," the review asks what percentage of those practicing unprotected sex did not know the status of their partner and notes the need to define "unprotected sex" in an era when ART that suppresses viral load provides pharmacologic protection.
   Response: P. 20-21. The passage was revised and updated with new data noting HIV status of partner: "In 2011, an estimated 13% of MSM with HIV reported engaging in sex without a condom with male partners who were HIV-uninfected or whose infection status was unknown." Also, a standard definition of "unprotected sex" for the purpose of this report was added; it refers only to physical barriers so readers understand it does not encompass ART.

5. **Comment:** P. 17; Reviewer praises authors for avoiding the term "target" that he considers an overused and alienating framework.
   Response: The terms "directing" or "focusing" are used throughout the report.

6. **Comment**: P. 18. Regarding topics covered by this report (that includes "risk screening and risk reduction interventions), the reviewer notes that the lack of addressing sexual health is weakness of this report.
   Response: P. 24. This passage was revised to broaden its scope and frame in a more positive way: "Screening for behavioral, biomedical, and structural factors that enable HIV transmission and offering interventions that promote health and reduce the risk of HIV transmission." Several mentions of health sexuality and more positively framed language regarding sexuality, such as "practicing safer behaviors", instead of "reducing risky behaviors" are made throughout the report, particularly in Section 7 (Risk screening).

General comment

1. **Comment**: P. 16. Regarding the passage "minority of persons with HIV benefit from biomedical interventions that reduce their infectiousness and risk of exposure other to HIV," the reviewer notes this is not supported by evidence, may be incorrect, and suggests that people with HIV cannot benefit from these interventions.
   Response: P. 19. See Comment #2 above. This passage was revised and updated with new citations to note that many persons do not benefit from the full range of interventions: "Nevertheless, national data indicate that many persons with HIV do not benefit from the full range of biomedical, behavioral, and structural interventions that can reduce infectiousness and the risk of exposing others to HIV."

Comment from Thrun and Walensky

1. **Comment**: P. 27. Both reviewers suggested publishing a separate summary that only includes the recommendations that refers to this encyclopedic report.
   Response: P. 25. This revision notes, "This report will be concurrently published with 3 shorter summary documents that list the subset of recommendations pertaining to each audience: clinical providers, nonclinical providers, and staff of health departments and HIV planning groups who provide population-level HIV prevention and care services." These summaries will be finalized once HHS approves the final language of the report.

Section 2 - Methods

Comments from Walensky

1. **Comment**: P. 22. Regarding this passage, "…CDC and HRSA solicited input on the proposed scope and audience for the recommendations and the development methods through teleconferences with several co-sponsor stakeholder organizations: the National Institutes of Health, including the Office of AIDS Research, National Institute of Allergy and Infectious Diseases and the National Institute of Mental Health; the HIV Medicine Association of the Infectious Disease Society of America; the American Academy of HIV Medicine; the Association of Nurses in AIDS Care; the National Association of People with AIDS; the National Minority AIDS Council; and the Urban Coalition for HIV/AIDS Prevention Services," the reviewer asks if patients and community members were on the panel and if not, if they should be included.
   Response: P. 23 and 27. Perspectives of persons with HIV and community members who serve persons with HIV were incorporated in many ways. Representatives of National Association of People with AIDS, the National Minority AIDS Council; and the Urban Coalition for HIV/AIDS Prevention Services, and many community-based HIV service organizations provided extensive input during the April 2011 consultation and several rounds of review of drafts from 2011-2014. (See Appendix C for full list of organizations.) The Workgroup included a few persons with HIV who are employed by CDC or HRSA.

2. **Comment**: P. 24; Regarding the passage, "The writing group for each topic also reviewed primary evidence from peer-reviewed journals, abstracts from national and international HIV conferences, program reports, unpublished data from CDC, and policy and legal documents about HIV prevention from HIV service providers that had been published (or became available in draft form in the case of unpublished data) from 2000 to June 2013," the reviewer asked if the conferences should be listed.
   Response: For brevity, these conferences were not listed because very few citations from conference abstracts were used to support the recommendations and numerous published articles provided ample and higher quality evidence. Most conference abstracts were used to provide late-breaking information on intervention progress that external reviewers requested be added in 2014 (e.g., the Partners study that is now underway).

3. **Comment**: P. 25: Regarding the passage, "The statements in the source guidance that were used to support recommendation statements in this document included 1) explicit recommendation statements of unspecified or any strength (e.g.,"Persons with HIV should be offered service X"), and 2) indirect or passively phrased statements that implied a recommendation of unspecified strength (e.g.,"Persons with HIV benefit from behavioral risk-reduction counseling")," the reviewer questions if statements are supported by evidence from the literature vs. expert opinion are distinguished and notes this distinction is critical.
   Response: All recommendation statements in each section notes the sources used to support the recommendations, including existing federal guidance, evidence (described in the Evidence topic of that section), or expert opinion.

4. **Comment**: P. 26: Regarding the passage, "the diversity of evidence supporting the recommendations, including randomized trials about drug efficacy, experience from health department programs, and expert opinion," the reviewer notes that defining the support for each recommendation is important.
5. **Response**: See response to Comment # 3.

6. **Comment**: P. 27. Regarding the passage, "All recommendations that reflect an extension of a recommendation directed to one provider type to another provider type were labeled," the reviewer asks if the report notes how to educate non-clinical providers on such issues.
   Response: P. 31. All sections include a topic on Implementation Resources that directs readers to an on-line library of resources to support implementation of the recommendations. This includes training materials, fact sheets, and decision support materials for nonclinical providers. More materials will be added as they are developed. Many are being developed by CDC and its grantees that serve community-based organizations and health departments.

7. **Comment**: P. 29. The reviewer suggests that for recommendation based on federal source guidance, the report should indicate if the source guidance was based on published data, expert opinion, or other sources, and if based on data, should reference the data so readers need not refer back to the source guidance.
   Response: Unlike a focused clinical practice guideline about a single intervention, it is not possible to accommodate this suggestion in a report that compiles a massive number of recommendations about numerous interventions for several reasons. The data supporting many recommendations in the federal source guidance were not listed or were not explicit. Also, some writing groups did not reexamine or excerpt the data sources that supported recommendations in the source guidance. However, key data supporting the recommendations are noted in the Evidence topic in each section and live hyperlinks for all source guidance are listed so readers easily find supporting data in the source guidance.

Comments from Baker

1. **Comment**: P. 23. Lack of addressing sexual health is weakness of this document.
   Response: See response to Baker's comment # 6 on the Introduction.

2. **Comment**: P. 28. A flow chart or grid of various inputs into the document would be helpful.

Response: These were not included because it would be difficult to present the heterogeneous methods in which recommendations were developed for each section, multiple stakeholders, and numerous rounds of review in a simple graphic and would add length to already long document. Also, CDC reviewers requested many details in narrative format.

Comments from Thrun and Del Rio

1. **Comment**: P. 29. Reviewers advise a single Methods section, not section-specific Methods sections.
   Response: The methods were not identical for each section due to differences in ability to rely on existing federal source guidance and need to use primary evidence. Section 2 describes methods common to all sections whereas each section includes a short Methods topic that describes additional details that pertain only to that section. This topic describes search terms for supplemental narrative reviews that gathered information that had accrued since publication of the relevant federal source guidance or was need in the section Background or Implementation topics.

Section 3 – The Context of Prevention with Persons with HIV

Comments from Del Rio

1. **Comment**: P. 37 and 38. The reviewer states that emphasis on ART is insufficient and that report should stress that once persons are aware of their infection they should actively seek care and promptly start therapy for their health and for decreasing transmission risk.
   Response: Section 5, Linkage, addresses prompt linkage to care that enables initiation of therapy so this issue is not elaborated in Section 3. However, P. 34 includes general recommendations that enable HIV care (e.g., enrolling in health insurance.)

2. **Comment**: P. 37 and 52. The reviewer states that statement about eligibility for undocumented immigrants for care under Ryan White HIV/AIDS program is incorrect.
   Response: P. 57. This section was corrected as follows, "Some immigrants who are not yet United States citizens can receive HIV care through Medicaid or health insurance plans depending on how long they have resided in the United States. Undocumented immigrants can continue to rely on other federal and state HIV assistance programs (that do not specify eligibility requirements related to immigration status) if they can provide documentation required by these programs."

3. **Comment**: P. 31. Recommendations about avoiding discrimination are unnecessary.
   Response: P. 34. These recommendations were retained because they were requested by many reviewers, including persons with HIV, HIV advocacy and legal organizations.

Comments from Walensky

1. **Comment**: P. 32. The reviewer asks if the recommendations in "CDC. Recommendations for case management collaboration and coordination in federally funded HIV/AIDS programs. http://www.cdcnpin.org/scripts/features/CaseManagement.pdf" are based on data or expert opinion.
   Response: P. 35. Like most recommendations about program operations, most recommendations were based on expert opinion, laws, and program evaluations, not research.

2. **Comment**: P. 32, Box 3-A. Regarding the passage, "Become familiar with implications of HIV disclosure in local jurisdictions, including access to health and social services, partner notification laws, risk of prosecution intentional for HIV exposure, and discrimination," the reviewer asks if access to legal assistance and laws related to deportation (or lack thereof) should be added.
   Response: P. 34. The revised passage provides some of these additional details: "Become familiar with social and structural determinants of health that influence use of HIV prevention and care services; and federal, state, and local laws and policies that govern the following issues: rights, responsibilities, and protections of persons with HIV regarding disclosure of their HIV-infection status and the unintentional or intentional exposure of others to HIV; provider responsibilities regarding HIV case reporting, protecting confidentiality, obtaining informed consent for HIV services, avoiding discrimination, and any to inform persons about possible HIV exposure…"

3. **Comment**: P. 33; Regarding the passage, "Develop HIV surveillance data release policies and practices that define allowable uses of surveillance data for HIV prevention services in local jurisdictions (e.g., using surveillance data to identify persons with HIV who warrant linkage to HIV care services or partner services)," the reviewer asks if these policies need to be relayed back to providers so they can tell patients how surveillance data are used.
   Response: P. 37. This recommendation was added: "Make online summaries of HIV surveillance policies and practices available to nonclinical and clinical providers so they are aware of how HIV case reports are used to support HIV prevention and care and can inform their clients and patients." Also, Section 9, STD Services, includes a recommendation to inform persons with HIV that STD case reporting may prompt health departments to offer voluntary, confidential partner services in some jurisdictions.

4. **Comment**: P. 35. Regarding the passage, "These recommendations were based on a narrative review of published and gray literature in English from 2000–2012 using these terms," the reviewer asks that gray literature should be defined.
   Response: P. 38. The term "gray literature" was replaced with a list of sources that complemented the published articles found through indexed databases.

5. **Comment**: P. 37. Regarding, "In the U.S., several populations bear a disproportionate burden of HIV infection," the reviewer advised adding persons with mental illness.
   Response: P. 41. Persons with mental illness are noted in the paragraph below.

6. **Comment**: P. 37. Regarding the passage, "Low-income persons with HIV who lack health insurance and are not yet enrolled in or are ineligible for free HIV services, such as migrant

workers or undocumented immigrants, are unable to obtain HIV care or ART," the reviewer asks if migrants and immigrants should be noted as a population with high HIV burden.
Response: P. 41. These populations were not added as the list of populations with a high HIV burden were based on surveillance data that do not collect migrant/immigration status.

7. **Comment**: P. 41. Regarding the passage, "Minors may lack established health care providers, experience navigating clinical and non-clinical HIV services, or information needed to document eligibility for HIV services (e.g., family income records needed to confirm Ryan White HIV/AIDS Program eligibility)," the reviewer suggests noting risk of poor ART adherence as youth transition from pediatric to adult clinics.
Response: P. 45. The language on barriers to quality HIV prevention and care services among youth in Table 3-1 was revised to address age-appropriate services: "Factors may hinder access to... to age-appropriate specialty services (youth-friendly services).…"

8. **Comment**: P. 46. Regarding the passage, "Provider confusion or fear of violating these regulations may hinder or delay the provision of prevention services referring patients to risk-reduction services, HIV care specialists, substance use treatment, and other medical and social services that can influence HIV transmission," the reviewer advises adding delays in receiving ART that suppresses viral load and the need for patients to understand the benefits of this type of data sharing.
Response: P. 48. Language was revised as follows, "… some providers who are not familiar with regulations that protect the confidentiality of paper-based and electronic records may be overly cautious about sharing or withholding information and cannot inform their clients and patients about confidentiality protections. In some cases, this may delay important prevention and care services."

9. **Comment**: P. 53. Regarding the passage, "In 2011, however, the IOM warned of an alarming national shortage of skilled HIV prevention providers due to," the reviewer suggests adding providers of HIV treatment.
Response: P. 59. This passage was revised as, "In the face of these challenges, the IOM recommended that health departments, primary care providers, and others advocate to increase the number of HIV providers and to train non-HIV specialists in HIV care and treatment. IOM also recommended shifting some tasks across provider levels, e.g., physicians could share some ART adherence support functions with physician assistants, advance practice nurses, registered nurses, pharmacists, and health educators."

Comments from Thrun

1. **Comment**: P. 31 (text box). Reviewer suggests adding a recommendation to encourage enrollment in health plans to improving access to HIV and primary care.
Response: P. 34. Recommendations were revised to read, "support enrollment of persons with HIV in long-term health care coverage (through private insurance, Medicaid, federal or state medical assistance programs, or other methods) to hasten access to HIV treatment."

2. **Comment**: P. 34, text box. Regarding infrastructure strategies, the reviewer advises adding structural interventions that reduce HIV disparities, e.g., antipoverty initiatives, civil unions.

Response: P. 36, Box 3-A. The recommended strategies were revised to include structural interventions such as "Promote initiatives to expand access to and coverage of essential HIV prevention and care services, particularly enrollment in health insurance or medical assistance programs; and Participate in evaluations of how laws about criminalizing HIV exposure, same-sex marriage, possession of drug paraphernalia and other issues might influence disclosure, transmission, and use of HIV services, and apply findings." This federal government report does not make specific recommendations about endorsing legal same-sex marriage or civil unions because these are matters of state, not federal, law.

3. **Comment**: P. 34 (text box). The reviewer suggests revising to better align with services across the HIV continuum of care so that prevention and care services providers understand how their organization and own work can contribute to population-level NHAS goals.
   Response: P. 36. The list of recommended strategies for health departments and planning groups was revised to read, "Evaluate strategies to coordinate services provided by health systems, community organizations, and health departments and support use of effective strategies across the continuum of HIV of care."

4. **Comment**: P. 35 (text box). Regarding the recommendation, "Promote initiatives to expand access to affordable HIV services and increase the number of trained HIV prevention providers," the reviewer suggests adding a recommendation to promote access to primary care because more HIV prevention activities such as HIV and STD screening services occur in primary care settings than HIV care settings. The reviewer also suggests adding a recommendation that all state HIV programs should partner with state Medicaid programs, particularly in states that have expanded Medicaid coverage.
   Response: P. 36. Box 3 recommendations were revised to include 1) support of enrollment of persons with HIV in long-term health care coverage (through private insurance, Medicaid, federal or state medical assistance programs, or other methods) to hasten access to HIV treatment and 2) strategies that reduce HIV health disparities and improve access to HIV prevention and care services. Box 3-A was revised to address primary care and partnerships with Medicaid: 1) "Promote initiatives to expand the HIV prevention and care workforce through training of non-HIV specialists and sharing of tasks across provider types (e.g., nurses and pharmacists provide adherence support instead of physicians)" and 2) Promote initiatives to expand access to and coverage of essential HIV prevention and care services, particularly enrollment in health insurance or medical assistance programs.

5. **Comment**: P. 37. Regarding the passage, "At the community level, 'prevention centered on persons with HIV' encourages persons with HIV, community-based organizations, HIV prevention planning groups, health facilities, and health departments to work together to design, implement, and evaluate HIV prevention programs and services. For example, persons with HIV have worked with local housing authorities to advocate for "supportive housing" options and developed a patient "bill of rights" that details essential HIV prevention services for a local health system," the reviewer asks if the passage can be more explicit that personal health (lowering viral load) is a matter of public or community health (lower risk for transmission within a community).
   Response: P. 33. The Background topic was revised to add, "Service providers who understand these contextual issues are better prepared to…endorse the strategy of

"treatment as prevention," in which services for persons with HIV contribute to community well-being." On P 34, the recommendations for nonclinical and clinical providers (including health department staff who provide individual-level services to persons with HIV) were revised to recommend: " 1)Participate in comprehensive networks of providers, organizations, and health departments that serve persons with HIV" and 2) Collaborate with HIV service providers and community organizations to support adequate coverage and reimbursement for HIV prevention and care services."

6. **Comment**: P. 43. Regarding the passage, "Providers who do not negatively judge or discriminate against persons with HIV are more likely to create trusting relationships that encourage persons with HIV to adopt HIV prevention strategies, to elicit accurate sexual risk information, and to direct persons with HIV to appropriate prevention services," the reviewer suggests more positive phrasing such as "Providers should be supportive of safe sexual healthy lives." to set a higher bar for providers and underscore the issue of sexual health promotion that CDC should champion.
   Response: This passage was replaced with other passages that stress the positive role of providers in promoting sexual health. On P. 46, the topic on Ethical and legal issues that influence access to and use of HIV prevention and care services, reads:"Providers who are aware of these [ethical and legal] issues are better equipped to affirm the rights and responsibilities of persons with HIV and fulfill their own legal and ethical obligations. They are also more likely to direct patients and clients to appropriate services, support public health practice, and foster mutual respect and cooperation between persons with HIV, their service providers, and their communities."

7. **Comment**: P. 45. Regarding the topic on Privacy and Confidentiality Standards, the reviewer asks if there is a section that encourages the sharing of data across clinical providers serving a patient with HIV, e.g., a Ryan White case manager would benefit from information from the physicians regarding data of last visit and viral load level. The reviewer notes that there are legal restrictions to the sharing of this data, including HIPAA, but adds that structural issues pose a problem, e.g., insufficient investment in the needed health IT infrastructure, and historical attitudes from health department and clinical providers that HIV information cannot be shared with other providers. He adds that electronic medical records will revolutionize HIV and suggests this section describe how EMR data can be used and shared.
   Response: P. 37, Box 3-B on recommended strategies for health departments to improve infrastructure for HIV prevention and discourage inappropriate withholding of data that could be used to support the continuum of care. **"**Develop state and local HIV surveillance data release policies and practices that define and assure legitimate uses of surveillance data to monitor HIV prevention and care in jurisdiction (e.g., to identify populations or individuals with HIV that warrant being offered assistance with linkage to HIV medical care)." P. 48. includes new language on EMR that reads:" Use of confidential electronic medical records for managing patients with HIV has grown as a result of the Patient Protection and Affordable Care Act (ACA) and technology innovations. Once stripped of confidential information, data from these record systems can also be used for legitimate quality improvement and monitoring purposes, such as elucidating gaps in the continuum of HIV care within medical practices and health systems." Section 4, Linkage and Retention in care, describes a research study that used EMR to support retention in HIV care. However,

more detailed information on the new field of how to use EMR for supporting the HIV continuum of care is beyond the scope of this document. The on-line Resource Library (noted in the Implementation Resources topic in most sections) may include materials to support implementation of recommendations about retention in care, ART adherence, STD screening, and other interventions as they become available, including EMR tools.

8. **Comment**: P. 47. Regarding the passage, "Some health departments interpret these standards in ways that allow use of secure methods to identify persons with HIV who may benefit from HIV prevention services. Many states require reporting results of a person's first CD4 count and/or viral load tests, regardless of their values. By comparing the dates of these laboratory reports with the date of initial positive HIV test results, health departments can identify persons with HIV with no or irregular HIV care who warrant linkage-to-care services and partner services. Also, health departments can analyze surveillance data to identify communities with high "community viral load" that could be targeted for services that promote linkage and retention in care and ART initiation and adherence," the reviewer suggests this be expanded into its own section.
   Response: More details on how to use surveillance data to support the continuum of care are beyond the scope of this report but are addressed in a new resource now cited: CDC Data to Care Toolkit: CDC. Data to Care: Improving health and prevention—using HIV surveillance data to support the HIV care continuum.
   http://www.effectiveinterventions.org/en/HighImpactPrevention/PublicHealthStrategies/DatatoCare.aspx. However, P 46 includes new language on using and sharing of surveillance data: "CDC has issued standards for handling HIV surveillance data that minimize uses that might reveal the identity of persons with HIV (see Box 3-B, Section 3). This includes situations in which health departments use surveillance data to identify populations and/or individuals with HIV who have unmet HIV prevention needs. For example, HIV surveillance programs that track cases of HIV infection that are not followed by reported CD4 cell count test results (a marker of HIV medical care) can identify populations that may warrant being offered assistance with linkage to HIV care, if allowed by the jurisdiction. In jurisdictions in which surveillance data may be used to support an individual's health care, case reports may prompt health department disease investigation specialists to help HIV testing providers link case-persons to HIV medical care. Also, in states that require reporting of a person's sequential CD4 cell count and viral load test results, health departments can identify persons who have declining CD4 cell counts or increasing viral load who may warrant being offered more effective treatment or adherence support (see Sections 4, 6, 8, and 11 for recommendations about using HIV surveillance data to assess unmet HIV prevention needs.). A new CDC toolkit describes strategies that HIV surveillance programs and health departments can use to promote HIV prevention and care, including ethical considerations when using confidential surveillance data."

9. **Comment**: P. 48. Regarding the passage, "At the federal government level, the 2010 National HIV/AIDS Strategy supports the following actions (then lists NHAS goals)," the reviewer advises inserting language about how agencies, HDs and individual providers can align their work with NHAS priorities.
   Response: P. 53. This language was revised to increase emphasis on NHAS, "Many governmental and nongovernmental policies and programs determine the funding or

infrastructure for delivering HIV prevention and care services. The NHAS described several essential elements of HIV prevention and care that favor more holistic, comprehensive care, reduce gaps in the continuum of HIV care, and reduce the burden of HIV in the communities where the infection is most prevalent. The NHAS stressed the importance of using evidence-based strategies… (listed hereafter and described in detail in subsequent sections)."

10. **Comment**: P. 49 (text box). Add HIV screening to the list of services covered by CMS. **Response**: P. 54. Language was revised to read, "HIV and STD testing and treatment"

11. **Comment**: P. 51. Regarding the passage, "Over the next decade, the implementation of the Patient Protection and Affordable Care Act (ACA) will dramatically change the scope, delivery, and funding of prevention services for persons with HIV," the reviewer suggests adding a recommendation that all federally funded entities should work collectively on this. **Response**: P 34, Box 3 contains several revised recommendations related to the ACA for individual providers, health departments and planning groups, many of which receive federal funds. These include advice to "Support enrollment of persons with HIV in long-term health care coverage (through private insurance, Medicaid, federal or state medical assistance programs, or other methods) to hasten access to HIV treatment; the infrastructure of organizations, including a skilled workforce, that is needed to deliver, coordinate, or finance HIV prevention and care services; and strategies that reduce HIV health disparities and improve access to HIV prevention and care services."

    P. 36 now list several ACA-related strategies directed to 1) nonclinical and clinical providers to improve HIV prevention infrastructure (i.e., Build agency or health facility capacity to deliver HIV services through staff recruitment, training, retention, and task sharing; participate in comprehensive networks of providers, organizations, and health departments that serve persons with HIV; and collaborate with HIV service providers and community organizations to support adequate coverage and reimbursement for HIV prevention and care services) and 2) staff of health departments and HIV planning groups (i.e., Recruit new providers into HIV service networks and establish agreements that describe their roles in service delivery, reimbursement mechanisms, referral and linkage procedures, exchanging health information, and monitoring prevention outcomes; Evaluate strategies to coordinate services provided by health systems, community organizations, and health departments and support use of effective strategies; and Promote initiatives to expand access to and coverage of essential HIV prevention and care services, particularly enrollment in health insurance or medical assistance programs."

    P. 57 now includes new information on the ACA that relates to collaboration, "Reforms of the ACA enable more providers working in Ryan White-funded clinics to bill Medicaid, other medical assistance programs, or private health insurance for HIV-related services. Medicaid and private insurance plans can also cover costs of HIV medications for persons who now receive subsidized medications through ADAP. The ACA has also increased attention to primary care and prevention, communication and service coordination between providers, financial efficiencies, adoption of standards of care, and use of integrated electronic health records. It encourages states to enroll persons with HIV and other chronic

conditions who are eligible for Medicaid into "medical homes" that use teams of providers to coordinate care and engage patient support services."

Comments from Baker

1. **Comment**: P. 30. Regarding the passage, "Several issues shape the lives of persons with HIV, their ability to adopt HIV prevention strategies over their lifetimes, and their access and use of prevention services," the reviewer notes this section is not well structured and should include a short analysis with evidence about how each issue impacts the population. He adds that if the report provides little context, the recommendation section force providers to learn more and may unintentionally deter them from providing prevention services.
   Response: This section was substantially revised and gives examples of contextual issues that influence HIV prevention with persons with HIV. For brevity in an already long section, it relies on Table 3-1 to summarize these issues and refers to evidence supporting each contextual issue in Section 12. Also, the Special Populations topic of sections 4-11 cover unique population, policy, legal, and ethical considerations that influence HIV prevention.

2. **Comment**: P. 31. The reviewer suggests placing the recommendation boxes last and using a simpler format that does not make providers feel that they need to learn more.
   Response: P 34. The Recommendation boxes are consolidated early in each section because guideline development experts advise listing all recommendations in one place near the front of a section to speed understanding and highlight discrete action steps. Readers who want only a list of recommendations can also refer to one of three audience-specific summaries of recommendations that will be published with this report. Each one is targeted to a specific audience for this guideline: clinicians, non-clinical HIV prevention providers, or health departments/HIV planning groups. Also, the on-line Resource Library includes numerous practical decision-support tools that are focused on specific interventions and provider types.

3. **Comment**: P. 36. Regarding the passage, "Persons with HIV can play a critical role in preventing ongoing HIV transmission to their partners," the reviewer suggests adding an sentence about the historical role of people with HIV in responding to the epidemic that would help providers appreciate the central role persons with HIV play in prevention.
   Response: P. 39. This passage was revised as follows, "Since the HIV epidemic was first recognized in the United States more than 30 years ago, persons with HIV have played an unprecedented role in drawing attention to the health and social burden of HIV, advocating for HIV prevention and care services, and mobilizing social and legal reforms. This commitment has served as a role model for personal empowerment and shared decision making that has improved access to and quality of services for HIV and other diseases."

4. **Comment**: P. 36. Regarding the passage, "When serving persons whose goal is to adopt harm reduction techniques such as using new sterile injection equipment (instead of or in addition to substance use treatment), providers can offer referrals to syringe service programs," the reviewer notes that most southern states do not have syringe programs and that the role of legal prescriptions for syringes should be added.
   Response: P. 39. This passage is intended to present an example of how providers and persons with HIV can collaborate to develop prevention goals and is not meant to list all

harm reduction methods for IDU. For this reason, information about state variations in SSP and access to prescriptions for legal syringes are only covered in Section 7, Risk Reduction.

5. **Comment**: P. 38. The reviewer suggests adding adolescents and young adults to the list of populations that bear a high burden of HIV.
   Response: P. 40. Adolescents and young adults were added.

6. **Comment**: P. 39. Regarding the passage, "Low-income persons with HIV who lack health insurance and are not yet enrolled in or are ineligible for free HIV services, such as migrant workers or undocumented immigrants, are unable to obtain HIV care or ART," the reviewer notes that undocumented persons can use Ryan White and other government services.
   Response: See response to Comment #2 from Del Rio for corrected language.

7. **Comment**: P. 38. Regarding the passage, "Transgender persons with HIV may be unable to find HIV providers or fear being stigmatized because of their gender," the reviewer suggests revised to read "gender identity."
   Response: P. 41. Language was revised to read: "some transgender persons fear their gender identity will provoke stigma from health care providers"

8. **Comment**: P. 40; table 3-1. Regarding the passage, "Fear of discrimination or prosecution for intentional HIV exposure may deter seeking HIV care, housing, employment, and other resources that can promote ART use, adherence, and safe behaviors," the reviewer suggests that if the fear discrimination is based on concerns about intentional HIV exposure, it would be better to phrase as "laws that criminalize sexual and other behaviors as acts of intentional HIV exposure may deter ..... Detention or incarceration can result in sexual violence, sharing drug-injection equipment, or interrupting HIV care, ART use, substance use treatment, and other treatment and prevention services. In jurisdictions where sex work is illegal, sex workers may defer seeking of HIV prevention and care services or use of prevention interventions that may prompt prosecution (e.g., when carrying condoms is used as evidence of sex work)."
   Response: P. 44. We revised examples under the header "Legal issues" to note that criminalization laws may deter possession or use of condoms and sterile syringes, voluntary HIV disclosure, and use of HIV care and other services that can promote ART use and safe behaviors.

9. **Comment**: P. 40; Regarding the passage in Table 3-1, "Ineligibility for driving license or valid photo identification may preclude access to HIV care and prevention services," the reviewer asks if lack of a driver's license been documented as a barrier.
   Response: P. 44. Because data on the role of drivers' licenses are sparse, the language on driver's licenses was deleted.

10. **Comment**: P. 43. Regarding the passage, "Persons with HIV who feel stigmatized or face prejudice may also experience housing or employment discrimination, denial of medical or dental care, or indifferent or substandard care," the reviewer suggested it be revised to read "are stigmatized."

Response: P. 50. The passage was clarified to read, "Some persons who wish to avoid real or perceived stigma or discrimination may defer HIV testing, care, and prevention services."

11. **Comment**: P. 43. The reviewer suggested these changes to this passage. "Providers who understand how ~~why~~ persons with HIV may be ~~may feel~~ stigmatized or discriminated against may recognize the importance of complying with confidentiality requirements, encouraging persons with HIV to disclose their infection status to partners in ways that minimize negative consequences, and informing persons with HIV about the legal, social, and health implications of HIV disclosure."
Response: For brevity, this passage was deleted. However, P. 50 describes some consequences of stigma and discrimination that support the recommendation on P. 34 that all providers "encourage communication that does not stigmatize or negatively judge persons with HIV or their sex, gender identity, sexual orientation, sexual and drug-use behaviors, and medical or social characteristics." These consequences include physical or verbal abuse, social marginalization, psychological distress, depression, and other mental health problems.

12. **Comment**: P. 44. Regarding the passages, "The extent to which violations of HIV exposure laws are prosecuted depends in part on awareness of the laws by providers, persons with HIV, health departments who receive HIV and STD case reports, and the general public," and "Many persons with HIV are unaware of HIV disclosure requirements and exposure laws until they are notified by their provider or case manager," the reviewer asks if public awareness of these issues or news reports about disclosure or exposure laws are associated with increases in prosecutions.
Response: P. 50. This language was updated with new data on prosecution; however, these data do not address how awareness of disclosure requirements or exposure laws influence risk of prosecution: "Between 1986 and 2011, 33 states enacted HIV-specific laws that could be used to impose criminal penalties on persons who knowingly expose others to HIV. These laws are controversial and have been subject to intense public debate. Most were passed before 2000, a period when the use of ART to reduce HIV-related disease, death and transmission was less prevalent. Of these 33 states, 27 specifically criminalize behaviors that pose a high risk of HIV transmission, including anal or vaginal sex, prostitution, and donating blood, tissue, or body fluids. Additionally, 25 states have laws that criminalize behaviors that pose negligible or no risk of HIV transmission, such as spitting or biting. Many of the 33 states specifically criminalize behaviors when persons have not disclosed their HIV infection to sex partners (24 states) or drug-injection partners (14 states). Few of these laws allow defendants to claim use of ART, condoms, or other prevention measures in their defense against criminal liability. In 28 of these 33 states, violations of HIV-specific criminal laws are classified as felonies and prison sentences can range from 1 to 20 years."

13. **Comment**: P. 44. Regarding the passage, "The extent of prosecution also depends on the availability of less punitive strategies to mitigate harm and prevent future violations and public opinion about the benefits of prosecution to individuals and society," the reviewer asks if this is true for all jurisdictions.
Response: P. 50 cites new data on prosecution that do not address how prosecution varies by the availability of other strategies to mitigate harm: "National databases cannot readily estimate the number of state-level prosecution, arrests, or plea agreements related to these

HIV-specific criminal laws. However, one evaluation of 186 arrests or prosecutions related to HIV from 2008 to January 2014 found that about 80% occurred under such laws."

14. **Comment**: P. 44. Regarding the passage, "the punitive potential of these laws may deter some persons with HIV from disclosing their infection status to their providers, from seeking HIV prevention services or care, and from notifying HIV-uninfected partners about methods to reduce risk of HIV acquisition after exposure (e.g., post-exposure prophylaxis)," the reviewer questions if there is good evidence to support this statement and if the lack of disclosure to providers vs. lack of disclosure to sex partners poses the greatest harm.
Response: P 48 and 51. This passage was revised in two ways 1) by noting that, "State laws about HIV disclosure vary in scope and degree of enforcement. Many require that persons with HIV notify their sex or drug-injection partners, including spouses, after they have received an HIV diagnosis" and 2) by placing more emphasis on risks of non-disclosure to sex and drug partners: "The impact of HIV criminalization laws on HIV disclosure, use of health department partner services, or HIV transmission is not known. However, several studies have concluded that these laws may not deter HIV risk behaviors and may cause significant or unintended harms. Harms may include resistance to HIV testing and self-disclosure or forcing persons to choose between the risk of prosecution for undisclosed sexual HIV exposure and the risk of intimate partner violence after disclosing their HIV infection. For these reasons, the 2010 National HIV/AIDS Strategy (NHAS) stated that it may be appropriate for legislators to consider if existing criminalization laws in their jurisdictions advance the public's interest and health. Some health policy experts have proposed revising these laws to limit prosecution to persons in whom intent to harm or high risk of intentional transmission has been demonstrated, such as through sexual assault or practicing prostitution without using condoms."

15. **Comment**: P. 44. Regarding this passage, "These [exposure] laws may also deter providers from offering STD screening or partner services because of concerns that reporting positive STD tests by clinicians or laboratories may prompt reporting of unprotected sexual activity to legal authorities, the reviewer notes this statement should be supported by some evidence.
Response: This passage was deleted because it was supported only by anecdotal reports.

16. **Comment**: P. 44. Regarding the passage, "Although clinicians, non-clinical providers and health departments cannot provide persons with formal legal counsel regarding HIV, they can inform persons with HIV about local disclosure requirements, exposure laws, and requirements to report HIV and STD diagnoses and test results to public health or legal authorities," the reviewer asks if this overstates the risks of STD reporting. He also asks that "legal authorities" be defined and a link be added for state-specific laws on disclosure.
Response: P 51. The passage was revised to read: "Health professionals and staff of health departments can play a valuable role in informing persons with HIV about legal requirements concerning disclosure and referring clients and patients to legal resources if prosecution is possible; however, they cannot provide legal counsel. These professionals can also help persons with HIV to engage health department assistance to notify partners (especially if physical or verbal abuse is possible) and to take steps to prevent exposing others to HIV in the future." An Implementation Resource topic was added that includes a link to an on-line Resource Library that includes information on state statutes about HIV criminalization

http://aids.gov/hiv-aids-basics/just-diagnosed-with-hiv-aids/talking-about-your-status/do-you-have-to-tell/. Section 9, STD Services, also includes a recommendation to inform persons with HIV who are diagnosed with STD that case reporting may prompt health departments to offer voluntary, confidential partner services in some jurisdictions.

17. **Comment**: P. 47. Regarding the passage, "Many [government policies and programs that fund or deliver HIV services] are expected to evolve in the next decade depending on implementation of the Affordable Care Act," the reviewer indicates this is vague and merits more detail now that ACA implementation is underway.
    Response: P. 57-58. The passage on the ACA was extensively revised based on events over the last 18 months. It briefly mentions funding of HIV care, expanded coverage for preventive and clinical services through Medicaid or private health plans, limits on insurer's ability to discriminate on the basis of HIV and other preexisting conditions, Medicaid expansion, and the impact of ACA on Ryan White service providers and billing methods, increased emphasis on primary care, medical homes, and care coordination for persons with HIV. More detailed discussion of this complex subject is beyond the scope of this report.

18. **Comment**: P. 49. The reviewer advises using correct program names for federal agencies.
    Response: The latest program names are now listed in the Table 3-2.

19. **Comment**: P. 49 (Table 3-2). The reviewer questions the table's purpose of the table and notes it is top-heavy on government agencies and does not note private-sector and community efforts in areas the government agencies cannot fund or work.
    Response: P 54. The table lists only selected examples of services and is not comprehensive. It emphasizes federal programs because the document is intended for a national audience that would apply to all states. However, we added examples of state, local, and non-governmental agencies that provide services, including ones federal programs do not fund such as syringe service programs, housing programs and legal counsel services.

20. **Comment**: P. 49-50 (Table 3-2). The reviewer notes that the listed services should include the role of community groups in peer support, education, and legal services given the extensive discussion about the impact of stigma and discrimination in this section.
    Response: p 54. The table was revised to include other non-medical services that can address psychosocial issues, stigma, and discrimination such as housing, food, transportation, legal services, peer support and case management.

21. **Comment**: P. 52. Regarding the passage, "It is expected that over the next several years many low-income persons with HIV currently receiving services through the Ryan White-funded clinics will receive care from providers affiliated with Medicaid plans on state Health Benefit Marketplaces who do not practice in Ryan White-funded clinics," the reviewer indicates that this under debate and has not proved to be the case in Massachusetts or DC where health reform has been long underway. He adds that lack of Medicaid expansion, especially in the South, and restrictive provider networks or ART formularies, may limit access to experience HIV care providers and certain ART regimens for low-income persons and that some Ryan White program components will be needed in the next few years.

Response: This passage was extensively updated to read: "Despite anticipated improvements in HIV services due to ACA implementation, troubling gaps in access to HIV prevention and car services may persist and may delay implementation of recommendations in this report. As of early 2014, some states have deferred expansion of state Medicaid programs. This may impair access to HIV medical care, particularly in Southern states where many low-income persons with HIV reside. More persons with HIV will receive care from the growing cadre of primary care providers serving enrollees of private insurance or Medicaid, many of whom have not yet obtained extensive HIV training and experience or forged relationships with other professionals who can provide risk reduction, case management, and other services that comprise a comprehensive "medical home." Medicaid and private insurance plans may not cover many valuable services now covered by the Ryan White HIV/AIDS Program or other special HIV programs. These include individual assistance with linkage to and retention in HIV care; case management; some types of ART adherence support; substance use and mental health treatment; and support for transportation, housing, and employment. Medicaid and private insurance do not cover some core public health activities, such as partner notification, that can prevent HIV transmission. Some antiretroviral medications covered by ADAP may not be covered by or included in drug formularies of private health insurance plans or have prohibitive copays….To address these gaps, the Centers for Medicare and Medicaid Services (CMS) and HRSA are working at the federal level to provide technical assistance to Medicaid agencies and Ryan White HIV/AIDS Programs. "Safety net" programs—such as the Ryan White HIV/AIDS Program and ADAP—will continue to provide essential HIV services in the years ahead. HRSA is also seeking to expand the successful "medical home" initiative used in Ryan White-funded clinics by offering training in HIV prevention, care, and treatment and HIV-related mental health and cultural competency to health centers without this expertise. Also, state and local health agencies and HIV planning groups that monitor HIV service delivery, health outcomes, and coverage policies in their jurisdictions can identify coverage gaps during this transition and advocate for relevant coverage expansion."

22. **Comment**: P. 53. Regarding the passage, "Under the ACA, some low-income patients with HIV have the option to transition from Ryan White HIV/AIDS Program provider teams that provide comprehensive "medical homes" with special HIV expertise to Medicaid providers, some of whom have limited HIV training and experience," the reviewer notes that ACA encourages Ryan White funded agencies or providers to accept Medicaid or other insurance. **Response**: P. 57-58. This passage was revised to read: "Under ACA reforms, more low-income persons who have received services in Ryan White-funded clinics can receive care from other providers affiliated with Medicaid or private insurance plans….More persons with HIV will receive care from the growing cadre of primary care providers serving enrollees of private insurance or Medicaid, many of whom have not yet obtained extensive HIV training and experience or forged relationships with other professionals who can provide risk reduction, case management, and other services that comprise a comprehensive "medical home." Medicaid and private insurance plans may not cover many valuable services now covered by the Ryan White HIV/AIDS Program or other special HIV programs."

23. **Comment**: P. 54. Regarding the passage, "Ryan White HIV/AIDS Program, Medicaid programs, private health plans, and HIV prevention planning groups could also formally

collaborate to recommend adequate provider reimbursement for prevention services," the reviewer notes it is odd that CDC-funded prevention agencies such as community-based organizations and health departments are not mentioned and that the section does not cover how these agencies could better connect with healthcare systems, especially if they could mobilize lower cost strategies.
Response: P. 59. This passage was revised to read: "Nonclinical HIV prevention providers in community-based organizations and health departments will continue to lead crucial HIV prevention and care programs. These organizations have provided HIV testing, risk-reduction interventions, and partner services for decades; many are now helping persons with HIV engage in HIV medical care and support ART adherence with funding from CDC and other sources. For example, one state health department is tracking case-specific CD4 cell counts and viral load measures reported to HIV surveillance as a means to identify persons who have had lapses in HIV medical care and may warrant help to resume care. HIV planning groups can foster the development of a skilled HIV prevention and care workforce by supporting training programs, adequate provider reimbursement for HIV services, and use of the most effective and cost-effective interventions." More detailed descriptions of how community-based organizations and health departments can collaborate with clinical providers to support HIV prevention is addressed in the subsequent sections of the report.

Section 4 – Linkage to and Retention in HIV Medical Care

Comments from Del Rio

1. **Comment**: P. 58; The treatment section does not adequately highlight the DHHS treatment guidelines. For example, page 58 should say "Currently the DHHS guidelines recommend initiation of ART for all HIV infected individuals regardless of CD4 count."
   Response: Section 5, Treatment, describes the HHS guidelines to initiate ART for all infected persons regardless of CD4 count so is not repeated here

2. **Comment**: P. 59. Box 4 should mention ARTAS intervention.
   Response: P. 67. Writing group prefers to recommend generic linkage interventions (as per second bullet) instead of a single intervention because many programs indicate that ARTAS model is not practical in many settings, especially nonclinical testing sites. However, ARTAS is noted in the topic on Evidence supporting these recommendations.

Section 5 – Antiretroviral Treatment for Care and Prevention

Comments from Del Rio

1. **Comment**: P. 83. The reviewer recommends that the passage "to prevent and/or treat HIV....." should be rephrased to read only "treat" HIV. He also notes that "Mixing ART for prevention and for treatment is incredibly problematic and confusing."

Response: Throughout the report, ART is described as a means to treat HIV and to prevent HIV transmission because it is effective for both purposes and is recommended by HHS for both purposes. Although the focus of this report is HIV prevention, the use of ART for treating HIV is invariably included as a primary indication some persons would not consider it ethical to prescribe ART for prevention purposes only.

2. **Comment**: P. 82, Box 5: The reviewer asks why a recommendation is needed to "inform patients on limitations and risks of ART" and asks "What are the limitations and risks?"
   Response: P. 89. The workgroup retained this recommendation because principles of informed consent warrant discussion of limitations of a long-term drug regimen that requires high adherence, may incur high personal costs, and may not eliminate all transmission risk.

3. **Comment**: P. 82-83: The reviewer notes that the treatment section does not highlight HHS recommendations to initiate ART regardless of CD4 count.
   Response: P. 88-89. The Background and Recommendations were revised in several places to stress that ART should be prescribed to all persons with HIV regardless of CD4 count.

4. **Comment**: P 90-91. The reviewer notes the Methods topic is redundant with Section 2.
   Response: As noted above, this topic is not redundant with Section 2. It adds new information and elaborates on how the systematic review and meta-analyses gathered from the PRS database (generally described in Section 2) focused on treatment issues.

Comments from Walensky

1. **Comment**: P. 82. Reviewer advised adding information on importance of adherence to ART and retention in care.
   Response: P. 89. Several recommendations were revised to emphasize these points.

2. **Comment**: P. 82. Regarding the passage, "Inform all HIV-infected persons (and their HIV-uninfected partners, if served) of the availability of two different prophylactic regimens, non-occupational post-exposure prophylaxis and pre-exposure prophylaxis…," the reviewer suggested listing PrEP before nPEP because PrEP is recommended and nPEP is not.
   Response: Throughout the document, PrEP is noted before nPEP. Text was also revised to clarify that nPEP is recommended only after isolated, inadvertent exposure, but not as a regimen for sustained protection against infection.

3. **Comment**: P. 83. Regarding the passage, "Offer ART according to U.S. Department of Health and Human Services (DHHS) recommendations to persons with HIV regardless of CD4 count," the reviewer advised stressing these are treatment guidelines.
   Response: This and other sections note that HHS recommends ART to treat HIV and, secondarily, to prevent HIV transmission.

4. **Comment**: P. 83. Reviewer suggested track change to read as "to <u>treat</u> ~~prevent~~ and/or ~~treat~~ <u>prevent</u> HIV-related disease"
   Response: P. 89. Change accepted.

5. **Comment**: P. 83. Reviewer suggested track change in text box as follows, "understand the need for long-term follow-up, retention and adherence."
   Response: Revision was accepted as per response to Comment #1 by Walensky

6. **Comment**: P. 83. Reviewer raised questions about the emphasis on treatment vs. prevention in this footnote, "As of May 2012, the U.S. Food and Drug Administration (FDA) had approved use of antiretroviral medication for treating HIV-infected persons but not for preventing HIV transmission from HIV-infected persons."
   Response: P. 90. This footnote was revised to distinguish FDA labeling and HHS-recommended ART use: "The U.S. Food and Drug Administration (FDA) had approved the use of antiretroviral medication for treating HIV-infected persons. The cited source guidance recommends use of ART for HIV treatment and for reducing the risk of HIV transmission."

7. **Comment:** P. 85. The reviewer notes that the content in Box 5-A regarding "Important points to consider when counseling persons with HIV about initiating or resuming ART" is redundant with recommendations in Box 5 for clinical providers.
   Response: P. 91. Box 5-A was retained (with abbreviated content) because it pertains to both nonclinical providers and clinical providers.

8. **Comment**: P. 85. Regarding Box 5-B, "Important points to consider when informing persons with HIV about medication their HIV-uninfected partners could take to reduce their risk of HIV acquisition," the reviewer notes that there are few data about when PrEP users should stop using PrEP and request this is mentioned.
   Response: P. 92. This report only includes basic information about PrEP that is relevant to providers serving persons with HIV who may inform their HIV-uninfected partners about the availability of PrEP. A discussion of indications for terminating PrEP use is beyond the scope of this report. This is addressed in CDC guidance on PrEP noted as a source guidance.

9. **Comment**: P. 87. The reviewer notes that DHHS and HHS are both used.
   Response: Throughout the document, HHS is used as per CDC Style Guide.

10. **Comment**: P. 87. Regarding the passage, "Future studies will assess the balance of positive and negative consequences of initiating newly recommended ART regimens at higher CD4 counts," the reviewer suggests adding information on the value of early ART for preventing non-communicable and neurocognitive diseases.
    Response: P. 97. The Evidence topic was revised to include this passage: "An ongoing RCT is directly comparing the benefits and risks of starting newly recommended ART regimens at >350 cells/mm^3 versus >500 cells/mm^3,[58] including chronic diseases that are relatively common in persons with chronic HIV infection but are not typically associated with immunosuppression."

11. **Comment**: P. 88 and P. 93. Regarding the passage, "Long-term ART is costly with annual drug costs exceeding $10,000", the reviewer asks if this figure is a per drug cost and notes it is too low for the cost of a full regimen.

Response: P. 98. This passage was revised to read: "The annual, unsubsidized cost of ART regimens recommended by HHS as of 2014 exceeds $10,000." and cites data from the May 2014 HHS ART regimens. It adds that co-insurance and co-pays for ART may be costly.

12. **Comment**: P. 88. Regarding the passage, "Financial access to affordable ART for persons with HIV and nPEP and PrEP for HIV-uninfected partners is a continuing challenge that may limit full implementation of these recommendations,", the reviewer advises discussing drug financing.
    Response: P. 98. This passage was revised as follows: "As of 2014, many options can substantially reduce out-of-pocket costs of ART, including Medicaid and Medicare, state ADAP, private sector health insurance, health care exchange plans initiated under the Patient Protection and Affordable Care Act (ACA), and pharmaceutical company drug assistance programs. Increased enrollment in health plans with pharmacy benefits and near elimination of state ADAP waiting lists (as of April 2014) has improved access to subsidized ART. Nevertheless, it has been estimated that under the ACA's health care exchange plans, coinsurance for ART may be substantial, with up to 55% of plans requiring patients to pay an average of 35% of their total ART cost. Federally funded programs, such as the Ryan White HIV/AIDS Program and ADAP, will remain crucial sources of affordable HIV care and ART in states that have not yet expanded the populations of low-income or disabled persons who are eligible for Medicaid."

13. **Comment**: P. 89. Regarding the passage about CDC interim recommendations about PrEP use, "This recommendation was intended for heterosexual persons (based on the highest level of evidence, a randomized trial of heterosexual men and women), MSM (based on expert opinion that ART-induced reduction in viral load would reduce sexual transmission between men), and PWID (based on expert opinion that ART-induced reduction in viral load would reduce transmission related to sharing [drug-injection equipment)," the reviewer advises adding that studies of PrEP were based on heterosexual couples in serodiscordant relationships and that FDA has approved PREP use.
    Response: P. 90-91. Details on evidence supporting PrEP recommendations for specific risk groups were omitted; it is detailed in May 2014 HHS PrEP guidance. A footnote about FDA approval of PrEP to reduce sexual HIV acquisition was added, "In July 2012, FDA approved one PrEP regimen (tenofovir/emtricitabine) for preventing sexual transmission. Although HHS recommendations in May 2014 advised use of this same regimen for persons who inject drugs (PWID), the product label only addresses use for preventing sexual transmission."

14. **Comment**: P. 90. Regarding the passage, "These recommendations were based … the Centers for Disease Control and Prevention (CDC) interim recommendations on use of PrEP by MSM, heterosexual persons, and PWID at high risk of HIV acquisition," the reviewer suggested noting that the PrEP guidelines will be updated soon.
    Response: P. 93. The revision cites the May 2014 PrEP recommendations, not the superseded interim recommendations.

15. **Comment**: P. 91. Regarding the topic called "Evidence Supporting the Recommendations," the reviewer indicates this is redundant with earlier passages.

Response: P. 95. The Evidence topic includes a brief summary of key studies that underpinned the federal source guidance that served as the basis for most recommendation s in this section as well as a few additional citations requested by other external reviewers. The Background section was trimmed of similar information to avoid redundancy.

16. **Comment**: P. 93. Regarding this passage, **"…** even though early initiation incurs greater lifetime antiretroviral drug costs than delayed initiation, early therapy reduces the costs of care for AIDS- and non-AIDS–related morbidity and reduces mortality," the reviewer notes that reference 61 is outdated.
    Response: P. 97. Reference 61 was replaced with two guidelines that provide a summary of data supporting early ART initiation, the latest HHS ART guidelines and the 2012 IAS Treatment Guidelines.

17. **Comment**: P. 93. Regarding the passage, "Comparisons of the lifetime healthcare costs of persons starting ART with CD4 counts at 350 to 500 cells/mm3 and persons starting ART with CD4 counts >500 cells/mm3 have not yet been reported,[3]" the reviewer suggests adding this reference: Sloane et al, JAIDS 2012 for data from France.
    Response: This citation was not added because costs in a single payer health system such as found in France are not relevant to the US.

18. **Comment:** P. 103. Regarding the Limitations topic, the reviewer states that the overall structure is redundant and much of the material is already familiar.
    Response: P. 95. See response to General Comment #2 from Del Rio regarding reframing limitations as a new topic entitled "Implementation progress, challenges and opportunities." It is not surprising that this material is familiar to this reviewer who is an expert in HIV care and prevention. However, it may be unfamiliar to other audiences for this report: primary care clinicians without HIV experience, nonclinical providers, and health department staff.

Section 6 – Antiretroviral Treatment Adherence

Comments from Del Rio (None)

Comments from Kalichman

1. **Comment**: P. 100 and 108. The report should add more information on the role of food insecurity, a leading adherence barrier that is more important than substance abuse.
   Response: P. 113. Dietary restrictions are noted as a barrier to adherence in Table 6-1 that summarizes data from systematic reviews of correlates of low adherence and factors noted by an HHS review, neither of which included 2014 studies. However, these sources did not identify food insecurity as a barrier. However, food insecurity is noted as an adherence barrier (with citation to the reviewer's work) in Table 12-1, Section 12 because this section was based on a narrative review of studies through 2014, including those that were not identified in the systematic review used for Section 6.

2. **Comment**: P. 102. Regarding the recommendation, "Stress that even individuals with undetectable viral load in the blood may still transmit HIV because their viral load may have

changed since their last measurement and results of tests for viral load in the blood do not measure viral load in genital secretions," the reviewer suggests adding information on the importance of informing persons that STI may increase genital viral load due to genital inflammation, despite adherence to ART.
Response: P. 106. The report was revised to include a recommendation to advise patients about "The possibility of HIV transmission even when virus is not detectable in the blood because blood measurements may not reflect viral load in genital and anal fluids or may have increased since last measurement," because the reviewer notes that STD-related local inflammation can increase genital viral load. The Evidence topic of Section 5, Treatment, includes this passage "Some STDs that cause genital inflammation may also increase shedding of HIV into semen and into cervicovaginal secretions, even in persons with low or undetectable plasma viral loads (see Section 9, STD Services)."

Section 7 – Risk Screening and Risk-reduction Interventions

Comments from Baker

1. **Comment**: P. 120. Regarding the recommendation for providing information about risk-reduction strategies, reviewer suggested adding, "if treatment naïve – the benefits of treatment for both health and prevention"
   Response: P. 128. Statements have been added to emphasize importance of ART and other biologic factors. Also the header for those statements was revised to read: "Provide or make referrals for risk-reduction strategies to persons with HIV (and to partners they refer) that emphasize healthy sexuality and avoiding substance abuse."

2. **Comment**: P. 123. Regarding this text "Provide staff training on state laws and requirements related to confidentiality protections, sharing of health information, HIV disclosure, syringe service programs, and intentional HIV exposure of sex or drug-injection partners," the reviewer notes that this terminology and the application of the law varies widely by state and advises rephrasing the passage about laws that criminalize HIV so it does not undermine public health.
   Response: P. 130. The passage was revised to stress "possible consequences" and refined the language to avoid undermining public health. Refined statement: "Provide staff training and tools that describe state laws and regulations about confidentiality protections, HIV disclosure and **possible consequences** of exposing others to HIV, minors' access to risk-reduction services, and ways to access legal, sterile drug-injection equipment."

3. **Comment**: P. 124, Box 7-C. Regarding topics related to risk-reduction, the reviewer notes this seems to be a long laundry list and advises stressing this is a list of suggested, not mandatory topics to address concerns of physicians that they do not have time or billing mechanism for longer visits to cover prevention issues.
   Response: P. 132. A footnote was added language to specify that these topics can be discussed over a series of encounters and non-verbal methods: "Providers can address topics relevant to each person with HIV using print, audiovisual materials, or discussion over **one or more** encounters."

4. **Comment**: P. 124**.** It would also be useful to provide a hyperlink to resources for discussing these issues [Risk-Reduction Topics] in the electronic version and have a guide to key resources as a sidebar in the print edition.
   Response: P. 132. The Implementation topic will include a hyperlink with many resources (including risk reduction topics) for all audiences for this guideline

5. **Comment**: P. 119. I suggest including HPTN 502 results for heterosexual couples.
   Response: P. 136. This study was noted earlier in this sub-section and addressed in more detail in Section 5.

6. **Comment**: P. 119. [Referring to a study**]** The reviewer notes that this data is potentially misleading unless it is restricted to HIV- discordant sexual partners and ask for additional detail on the infection status of partners.
   Response: P. 147**.** This study was replaced with two new studies presenting data on unprotected risk behavior in HIV-discordant couples and other information about partners: "A recent analysis of 2009 surveillance data found that among about 600,000 persons with HIV with unsuppressed viral load, 20% engaged in unprotected, serodiscordant risk behavior (a transmission rate of 23.13%). A meta-analysis of 30 U.S. studies that included more than 18,000 MSM with HIV estimated that 26% reported unprotected anal sex with partners who were HIV-uninfected or had unknown infection status (95% CI: 21–30%)."

7. **Comment**: P. 119. [Referring to the same 2009 surveillance study as previous comment] The reviewer asks if these infections occurred from people who knew they were HIV-infected at the time of sexual encounter.
8. **Response**: P. 147. The report does not address this point specifically. We therefore added another study that describes sexual activity by persons who knew their status at the time of the encounter.

9. **Comment**: P. 143. [Referring to Implementation Resources link] The reviewer notes this is important and advises it is organized so physicians can easily access tools to use in practice – including referrals to local programs and services. He adds that implementating evidence-based interventions (especially those demanding multiple sessions or group formats) may be impossible in private practices that face barriers to providing risk-reduction interventions.
   Response: P. 151. Because the resources are numerous and diverse, each one could be suitable for multiple provider types (clinicians, nonclinical providers who provide health education, health department staff that provide partner services). Therefore, the resources are stratified in the first edition of this Resources link will be stratified by domain (e.g., Risk-reduction, Treatment, etc.), not by provider type. Resources that could be used by private-sector providers will be included in this link, including the updated ***Prevention is Care*** materials being developed by CDC.

Comments from Kalichman

1. **Comment**: P P 124 [Referring to Box 7-C on Risk Reduction topics] and P. 128 (Box 7-D). The recommendations are out of date and default to an 'information-motivation-behavioral skills' model despite lack of evidence that information and education lead to sustained

behavior change. The motivational component is also limited given the current state of treatment as prevention, and the behavioral skills are irrelevant in the absence of managing contextual and structural factors. Thus, it is overly simplistic and misleading to suggest that individuals with HIV would reduce risk behaviors if only informed, motivated and educated in skills.
Response: P. 131**.** Box 7-D was removed due to the reviewer's concerns. P. 132. Biomedical strategies were added and emphasized in this Box 7-C and elaborated in Box 7-B (Risk Screening Topics)

Section 8 – Partner Services

Comments from Thrun

1. **Comment**: P. 149. In response to this passage, "Partner services comprise a broad array of voluntary services that should be offered to persons with newly diagnosed or newly reported HIV infection, to persons with established HIV infection who have new partners or a newly diagnosed sexually transmitted disease (STD) that may be a marker for unprotected sex…," the reviewer questions the value of partner services (PS) for **all** persons with chronic, established infection and new partners because many of these such persons protect their partners by using condoms and/or using ART to suppress their viral load. He adds that focusing on such persons may not be as high as priority for partner services as other persons with chronic HIV who do not use condoms or ART. He suggests that persons with chronic HIV who use condoms and/or ART may be better served by resources to encourage self-disclosure of their infection status, rather than PS.
   Response: P. 157. The Background topic was revised to stress the subset of persons with chronic infection that warrant PS. "This section focuses on HIV partner services for 1) persons with HIV (described as *index patients*) who have been newly diagnosed in clinical or nonclinical settings; newly reported to a health department; or previously diagnosed and also pose a high risk of exposing others to HIV (e.g., a recently diagnosed STD that indicates *unprotected sex* or may facilitate HIV transmission or sharing *drug-injection equipment*). The notion is reinforced on p 161 (Box 8) that notes that interviewing should be prioritized for index patients with… behaviors that pose a high risk of exposing others to HIV…"

2. **Comment**: P. 150, Box 8. The reviewer suggests revising the text to incorporate track changes, "For all providers including providers that provide HIV testing in clinical or non-clinical settings who identify persons with newly diagnosed HIV infection or persons with HIV who report new STD or ongoing high risk behaviors with sex or drug-injection partners, ~~including providers that provide HIV testing in clinical or non-clinical settings~~:
   Response: P. 161. The headers that define provider types and text revisions incorporate these suggestions.

3. **Comment**: P. 150. Regarding the passage, "Establish communication and collaborations with health departments, including routine HIV case reporting, to ensure that partner services are offered according to requirements of their jurisdiction and the Centers for Disease Control and Prevention (CDC) guidelines," the reviewer asks if this should refer to "relationships" that address not only legal relationships, but also build an understanding of

the people providing the services. The reviewer notes that providers would be more willing to report cases of HIV to health departments if they had long-term relationships with health department staff who provide PS and other services to persons with HIV. ON P 161, he suggests clarifying the types of collaboration that clinical and nonclinical providers can pursue with health departments

Response: The revisions details types of collaborations and relationships with health department staff that can reinforce knowledge and skills about HIV partner services regarding 1) Methods to ensure that services are voluntary and confidential; 2) Elements of partner services; 3) Roles, responsibilities, and legal authority of nonclinical providers, clinical providers, and health department staff to provide partner services to index patients and inform their partners of possible HIV exposure; and 4) Laws, regulations, requirements, procedures, and guidelines in the jurisdiction."

4. **Comment**: P. 150, 153, 160, 190, and 194. Regarding the recommendation to provider PS to "persons with established HIV infection who have a new sex or drug-injection partner", the reviewer notes this poses a high burden to PS providers because many persons with established HIV do not pose a risk of transmission due to condom use or adherent ART use.
   Response: P. 161. Revised Box 8 notes that interviewing should be prioritized for index patients with… behaviors that pose a high risk of exposing others to HIV…"

5. **Comment**: P. 151. The reviewer says the footnote that notes that providing partner services "Applies only to community-based organizations that have the capacity to provide these services," is not needed or should be revised to clarify that CBOs who do not have on-site PS capacity should refer clients to the health department.
   Response: P. 161, Box 8, clarifies that CBOs should refer clients to health department PS by recommending they 1) "Develop infrastructure, policies, and procedures that enable persons who are eligible for HIV partner services *(index patients)* to obtain services through the health department or other authorized providers." and 2) "Promptly refer index patients to health department partner services directly or through HIV case reporting according to the methods of the jurisdiction…" The confusing footnote was deleted.

6. **Comment**: P. 153. Regarding the recommendation to "Provide verbal, print, or audiovisual materials to index patients and partners that describe the value and process of partner services and the availability of free, voluntary health department services," the reviewer suggests adding a recommendation that health departments produce materials about PS for the providers in their jurisdiction.
   Response: P. 162, Box 8. The recommendations for health departments have been revised to include, "Collaborate with HIV testing providers in nonclinical and clinical settings and with HIV medical care providers to provide partner services information, resources, advice, and assistance." Also, P 163, Box 8-A, now includes a recommendations to "Offer provider and patient education materials that describe health department partner services and how they can be engaged" and "Staffing arrangements that expedite partner services at high-volume, high-prevalence HIV testing sites (e.g., assigning health department specialists to work onsite or on an on-call basis)."

7. **Comment**: P. 153 (text box). The reviewer recommends adding more information on appropriate staff development based on 2008 CDC partner services guidelines.
   Response: P. 163-164. The recommendations were revised to include, "Provide ongoing training to health department specialists on effective partner services methods that are informed by local epidemiology, jurisdiction requirements, and CDC guidelines…"

8. **Comment**: P. 155; Reviewer suggests changing "offering condoms" to "providing condoms"
   Response: P. 166, Box 8-B uses the less directive word "offers" condoms because not all clinical and nonclinical settings are able to provide free condoms to clients or patients.

9. **Comment**: P. 156. Regarding the footnote, "All of these source guidance documents advise providing information and counseling about condom use, but only HRSA guidance for persons attending publicly funded clinics specifies providing condoms, " the reviewer says that condoms should always be provided.
   Response: P. 167. Footnote is retained so that readers know that only one source guidance (for federally funded HRSA clinics) advises providing free condoms to patients or clients.

10. **Comment**: P. 157. The reviewer questions why each section includes a section on the limitations and risks of the recommendations as it erodes support for the recommendations.
    Response: P. 171-172. The Limitations section was reframed in a more positive way as "Implementation challenges" later in the Section.

11. **Comment**: P. 158-159. Regarding the passage, "Increased emphasis on collaboration between HIV surveillance programs and clinical, non-clinical, and health department disease prevention providers to ensure that all persons who test positive for HIV are offered partner services as soon as possible after HIV diagnosis or the diagnosis of an STD in an HIV-infected person," the reviewer questions if the recommendations adequately stress long-standing relationships between health department PS providers and sites that consistently identify a large number of people with HIV or STDs, or serve people with HIV, because PS specialists confirm the importance of these relationships.
    Response: See response to comment # 3 above. The recommendations were revised to stress relationships with health departments.

12. **Comment**: P. 161. The reviewer notes that some of the PS terms and definitions are confusing, such as *Provider referral notification and Third-party referral notification.*
    Response: P. 158. Many technical terms were deleted and clearer explanations were provided early in the section.

13. **Comment**: P. 162. The reviewer found this study description confusing. "The narrative literature review identified one small study that found that interviewing HIV-infected index persons within 2 weeks of their diagnosis was significantly more likely to result in identifying HIV-infected partners (only 8 index patients interviewed per newly identified HIV-infected partner) than interviewing index patients more than 2 weeks after their HIV diagnosis (21 index patients interviewed per newly identified HIV-infected partner)…"
    Response: P. 161. The passage was revised to clarify that earlier interviewing yielded more identified partners than delayed interviewing: "A small study in San Francisco evaluated the

effort to find 1 newly identified HIV-infected partner; health department staff had to interview only 8 HIV-infected index patients if their interviews occurred within 2 weeks after diagnosis, but had to interview 21 HIV-infected index patients if their interviews occurred more than 2 weeks after diagnosis (p=0.008)."

Comments from Marrazzo

1. **Comment**: P. 149. The reviewer questions why the mention of PrEP is limited to heterosexual persons and omits bisexual persons or women who have sex with women.
   Response: P. 160. The description of PrEP was revised to avoid specifying the sexual orientation of persons who have clinical indications for this regimen.

2. **Comment**: P. 151. Regarding the recommendation, "Promptly refer index patient (and their partners if served) to partner services specialists at health department," the reviewer suggests adding "if available" because these services may not be available in rural or remote areas.
   Response: P. 164, Box 8-A, includes a revised recommendation, "Establish criteria to prioritize interviewing of index patients based on available resources." P. 172 also adds a new passage on implementation challenges in rural areas with limited PS services.

3. **Comment**: P. 151; (text box). Reviewer suggests this change: "strongly counsel ~~urge~~ patients to notify partners that they should seek testing for HIV and clinical evaluation and testing for STD."
   Response: P. 166. This passage was revised to stress the importance of telling partners to obtain HIV and STD evaluation and testing: "If the index patient chooses to self-notify any partner without assistance, the provider should describe … Important messages for partners (e.g., how to obtain HIV, STD, and viral hepatitis testing and evaluation in clinical settings or nonclinical settings that link clients with positive tests to health care providers; home testing if the partners decline other testing options)."

4. **Comment**: P. 156, 159, and 190. Regarding passages that state "**not** to offer HIV-infected index patients with diagnosed STD expedited partner therapy (EPT) for their partners" because this approach does not include offering HIV testing to exposed partners and linkage to care assistance if partner is HIV infected, the reviewer advises checking for consistency with the recommendations about expedited partner therapy in the forthcoming 2014 STD Treatment Guidelines. She adds that while EPT is not optimal for such persons (because partners may not be tested for HIV), it may be preferable to no partner treatment.
   Response: This report no longer addresses EPT because the Director of CDC's Division of STD Prevention Division believes that the balance of benefits and harms of EPT for partners of persons with HIV, especially in MSM, remains uncertain and the nuances of EPT for persons with HIV are too complex to fully describe in this report.

   Comment: P. 158. Regarding the passage, "Clinicians rarely play a role in treating male sex partners of HIV-infected women diagnosed with trichomoniasis because treatment of male sex partners has not been shown to influence a woman's likelihood of relapse of recurrence,"

the reviewer notes that this contradicts the CDC STD Treatment Guidelines and does not adequately address the fact that treating the woman's partner(s) can help prevent reinfection.
Response: P. 161. The recommendations were been revised to be consistent with the latest CDC STD Treatment Guidelines, noting that female index patients with HIV who have been diagnosed with trichomoniasis should be prioritized for PS because this infection may signal unprotected sex and may facilitate HIV transmission. Also, Section 9, STD Services, P 186, includes a new recommendation to retest women treated for trichomoniasis 3 months later due to high risk of re-infection.

Section 9 – Sexually Transmitted Disease (STD) Services

Comments from Thrun

1. **Comment**: P. 169 (text box). Regarding the recommendation, "Inform persons with HIV about methods to reduce risk of HIV and STD transmission", the reviewer suggests adding "HIV acquisition" to stress risk of dual transmission (to and from someone with HIV)
   Response: This was not added because this section focuses on issues for the person with HIV, not their partners, which are addressed in the preceding section on partner services.

2. **Comment**: P. 169 (text box). Regarding the recommendation, "For persons with HIV and diagnosed STD or who report high-risk behaviors, provide or make referrals for behavioral risk-reduction interventions," the reviewer suggests adding a recommendation to refer persons for partner services.
   Response: P. 182. We revised the recommendation to read: "For persons with HIV who report sexual risk behaviors, provide or refer for brief or intensive behavioral risk-reduction interventions; refer to voluntary health department HIV partner services or other trained partner services provider if persons are newly diagnosed with HIV or report new sex partners…."

3. **Comment**: P. 169 (text box). The reviewer questions why there are no recommendations for health department staff and notes such recommendations could facilitate collaboration between clinical providers and HD staff.
   Response: P. 184 and 187. Recommendations for HD staff who provide individual level services (e.g., HD clinicians or community health educators) are covered under the headers for nonclinical and clinical providers. Specific recommendations for HD staff who provide population-level services were added in the Box 9: "For staff of health departments who provide population-level HIV prevention and care services, develop methods to integrate or routinely match HIV and STD surveillance case reports and use such surveillance data to routinely identify populations or persons with HIV who have new STD infections and may warrant being offered HIV and STD preventive services, including voluntary partner services; and support efforts to promote STD and HIV prevention for persons with HIV in community. Strategies for HD were described in Box 9-B, including 1) Educating providers and laboratories about the role of STD preventive services in HIV prevention; CDC recommendations for STD screening and treatment; benefits of screening MSM for gonorrhea and chlamydial infection in nongenital sites; gonorrhea drug resistance and the need for laboratory capacity for antimicrobial susceptibility testing; voluntary health

department partner services; and case reporting; 2) Educating community about local burden of STDs, populations with HIV at greatest risk for STD infection, and HIV-uninfected partners at risk for HIV and the role of STD preventive services in HIV prevention, and STD preventive services in clinical and nonclinical settings; 3) Increasing access to routine behavioral risk-reduction services, STD screening services, and condoms in clinical and nonclinical settings; and 4) Increasing the capacity of laboratories to screen rectal and oropharyngeal specimens for *N. gonorrhoeae* and *C. trachomatis* using NAATs and to monitor gonococcal antimicrobial drug resistance trends using culture tests.

4. **Comment**: P. 169 (text box), 217 and 219. Regarding the recommendation, "Treat all HIV-infected patients for specific STDs based on laboratory tests or clinical diagnosis and link or refer patients to partner services," the reviewer notes that this occurs at initiation of care and on an ongoing basis and suggest adding a separate recommendation on partner services.
   Response: P. 182-183. The recommendations have been revised in several places to stress the need for ongoing treatment and partner services if STD are diagnosed based on positive screening or diagnostic tests or clinical evaluation at the initial or later visits.

Comments from Marrazzo

1. **Comment**: P. 168. The reviewer notes that there is not enough information on diagnosing symptomatic STD, like syphilis.
   Response: P. 182-183. Several recommendations were revised to note the importance of provider or referring patients for a clinical evaluation for STD signs and diagnostic testing.

2. **Comment**: P. 168; (text box). Regarding the recommendation, "Assess persons with HIV for sexual behaviors that lead to HIV and STD transmission with a frequency appropriate to provider setting," the reviewer asks if frequency of assessment should be guided by the person's risk behavior and the results of the risk assessment, not the setting.
   Response: P. 182. This recommendation about the frequency of risk assessment was revised to read: "At the initial HIV-related encounter and thereafter with a frequency appropriate to risk assessment results, provide the following services…" This revision considers that results of risk assessment will drive repeated assessment in clinical settings that provide continuous care, but may be less instrumental in nonclinical settings that provide episodic care and rarely recall clients for repeated risk assessments.

3. **Comment**: P. 169 (text box). Regarding the recommendation, "For persons with HIV and diagnosed STD or who report high-risk behaviors, provide or make referrals for behavioral risk-reduction interventions," the reviewer suggests adding "if available" because many providers will not have access to such interventions.
   Response: P. 182. This recommendation was revised as follows, "Provide or refer for brief or intensive behavioral risk-reduction interventions" to clarify that interventions need not be lengthy, multi-session or provided on sight. This recommendation may encourage providers to offer brief risk reduction services on site, such as 3-5 minute messages shown to be effective in clinical settings.

4. **Comment**: P. 169. Regarding the recommendation to "Review current symptoms and recent diagnoses of STDs, including urethral, vaginal, anal, and oropharyngeal discharge …."" the reviewer notes oropharyngeal discharges do not exist.
   Response: P. 183. The recommendation was revised to note oropharyngeal exudate.

5. **Comment**: P. 171 (text box) and P. 172. Regarding the recommendations for STD screening and the initial HIV care visit and at least annually thereafter, the reviewer advises to highlight need for more frequent screening of MSM.
   Response: P. 185. The recommendation for more frequent screening of MSM was moved from a footnote to the text box for greater visibility and revised to reflect language of the latest CDC STD Treatment Guidelines.

6. **Comment**: P. 171 (text box). Regarding recommendations for gonorrhea and Chlamydia infection testing, "preferably using NAAT," the reviewer advises that all testing should be done using NAAT.
   Response: P. 185. This recommendation was revised to read "using NAAT", which is consistent with increased availability of NAAT testing in public and private labs in the U.S.

7. **Comment**: P. 171; (text box). Regarding the recommendation for "Retesting for chlamydia or gonorrhea 3 months after treatment, "the reviewer notes that the CDC STD Treatment Guidelines also recommend repeat testing for trichomoniasis 3 months after treatment.
   Response: P. 186. This recommendation was revised to recommend retesting after treatment for trichomoniasis although the 2010 STD Treatment Guidelines (on which most recommendations in this box were based) did not recommend such retesting. However, evidence that will support a recommendation for retesting after trichomoniasis treatment in the forthcoming 2014 CDC STD Treatment guidelines was used to support this recommendation and was described in the Evidence topic of this section.

8. **Comment**: P. 173; The reviewer suggests changing this passage, "These recommendations advise use of commercially available nucleic acid amplification tests (NAAT) to test rectal and pharyngeal samples for gonorrhea ~~and chlamydia~~ although use of such tests with rectal or pharyngeal specimens is not U.S. Food and Drug Administration (FDA)-approved," because oropharyngeal samples should be tested for gonorrhea but not for Chlamydia.
   Response: P. 191. The text was revised to read: "These recommendations advise use of sensitive, specific commercially available NAATs to detect gonorrhea in rectal and oropharyngeal specimens and chlamydial infection in rectal specimens, although use of such tests with rectal or oropharyngeal specimens is not cleared by the U.S. FDA."

9. **Comment**: P. 173. Regarding the passage, "Several laboratories have met all regulatory requirements for off-label procedures for testing rectal and pharyngeal specimens, but access to such laboratories is limited in many areas," the reviewer notes that these tests are widely available in national commercial labs but adds they are expensive.
   Response: P. 192. The passage was revised as: "Several state public health and national commercial laboratories have met all CLIA regulatory requirements for off-label procedures for testing rectal and oropharyngeal specimens and billing codes have been assigned."

10. **Comment**: P. 173. Regarding the passage, "Adoption of STD screening recommendations may be limited," the reviewer notes that despite the high incidence of STI in HIV+ MSM, appropriate screening in HIV care settings is very suboptimal and cites Hoover, STD, 2010.
    Response: P. 191. This passage was revised as follows, "STD screening is an underused prevention strategy despite the high incidence of STDs in some persons with HIV, particularly men who have sex with multiple male partners" and cites the Hoover reference.

11. **Comment**: P. 173; Regarding the passage, "Several factors may have contributed to low screening rates: limited access to or lack of insurance coverage for off-label NAAT testing, the necessity for invasive anal and genital specimen collection (unlike syphilis serology that can be collected during routine CD4 or viral load testing), lack of sexual behavior assessment that may prompt testing at rectal and pharyngeal sites, and competing clinical priorities," the reviewer claims this overstates the case because anal and vaginal swabs and urine specimens are not particularly invasive. She adds that provider reluctance to address sexual health due to inexperience and discomfort contributes to low screening rates.
    Response: P. 191. This passage was revised as follows, "Several factors may contribute to low screening rates: reluctance to collect anal and genital specimens (in contrast to syphilis serology that relies on venous blood specimens that are also used for CD4 cell count and viral load testing); incomplete sexual behavior assessments that fail to identify the need for testing rectal and oropharyngeal specimens; limited knowledge of NAAT tests for rectal and pharyngeal specimens (including how to access tests, seek insurance coverage, and apply billing codes); and competing clinical priorities."

12. **Comment**: P. 173. The reviewer notes she does not understand the point of this passage, "STD treatment rarely results in adverse reactions, but poor adherence can compromise the effectiveness of treatment."
    Response: P. 192. This passage was revised to alert readers to potential problem of adverse reactions and antimicrobial resistance as follows, "STD treatment is generally safe and effective and rarely results in adverse reactions. Emergence of antimicrobial-resistant pathogens may impair the effectiveness of some treatments over time."

13. **Comment**: P. 176. The reviewer suggests that the "Ask-Screen-Intervene" curriculum from CDC's Division of HIV/AIDS Prevention be included as an Implementation Resource.
    Response: P. 193. This resource will be added to the on-line Resource Library.

Comments from Kalichman

1. **Comment**: P. 225. The reviewer notes insufficient discussion of role of STI in increasing genital viral load in persons who adhere to ART and may have suppressed plasma viral load.
    Response: For brevity, this issue is addressed in Section 6 on Adherence and Section 5 on Treatment, (see response to comment #3 of Kalichman) and is not repeated here.

Section 10 – Reproductive Health Care for Women and Men

Comments from Walensky

1. **General comment** P. 186 and 189: For brevity, the reviewer suggests not repeating definitions in each section, but referring reader to Glossary.
   Response: Selected terms are defined in each section (in text or footnote) the first time they appear because external reviewers indicated that many readers will download or print only selected sections that need to "stand alone." Adding these definitions adds very little length to each section and engage broad range of readers, some of whom may have not attended college or have no clinical background.

2. **Comment:** P. 180. The reviewer suggests noting dual contraceptive use earlier in the section.
   Response: P. 198. Dual contraceptive use was added in several bullets in Box 10.

3. **Comment**: P. 180. Regarding the recommendations, "1) Inform sexually active, HIV-infected persons (or their HIV-uninfected partners, if seen) about the availability of nPEP to prevent HIV acquisition by HIV-uninfected persons after very recent sexual or parenteral HIV exposure; and 2) Caution that repeated or prolonged use of nPEP while attempting conception through unprotected intercourse is not recommended because information about the safety and efficacy of nPEP regimens when attempting conception and early pregnancy is very limited and other methods allow persons with HIV to conceive without repeated acts of unprotected sexual intercourse," the reviewer asks why one recommends nPEP and then advises against its use.
   Response: P. 198. The recommendation was revised to stress very limited use in couples who are attempting conception: "Inform persons with HIV (and HIV-uninfected partners referred by them) about the availability of nonoccupational postexposure prophylaxis (nPEP) for HIV-uninfected partners when clinically indicated on a one-time, nonrepeated basis to reduce the risk of HIV acquisition in the event of inadvertent sexual or parenteral HIV exposure within the past 72 hours (e.g., unprotected intercourse, condom breakage, shared drug-injection equipment)."

4. **Comment:** P. 191. Regarding the passage, "[HHS guidelines] advise that concerns about pharmacokinetic interactions should guide ART and contraceptive choices, but should not prevent providers from recommending hormonal contraceptives to women taking ART. Providers should inform women about potential interactions between ART and hormonal contraceptives and encourage concurrent use of male or female condoms to optimize prevention of pregnancy and HIV transmission," the reviewer suggests adding a recommendation about ART and contraceptive interactions in Box 10.
   Response: P. 199 and 208. This recommendation was added to Box 10: "Inform women with HIV who are using or considering using both ART and hormonal contraception about possible interactions between these two medication classes that might influence drug efficacy." The Evidence topic elaborates that HHS recommendations "advise that concerns about pharmacokinetic interactions should guide ART and contraception choices, but should not deter health care providers from recommending hormonal contraception to women on ART. These conclusions highlight the benefits of informing women about 1) potential interactions between ART and hormonal contraception…."

5. **Comment:** P. 183. The reviewer suggests stating that nPEP is not recommended as a routine when attempting conception to prevent risk of HIV acquisition.
   Response: P. 198 and 202. Based on HHS 2014 Perinatal Guidelines and 2005 nPEP guidelines, the writing group concluded that repeated courses of nPEP in couples attempting conception are not indicated, but that a single course after inadvertent, isolated exposures (such as sexual assault), is not contraindicated and is therefore noted in Box 10 and 10-A as noted in Response to Comment #2. (In fact, both 2005 and forthcoming CDC draft guidance about nPEP, as well as guidance about nPEP use from New York State, describe regimens for women who may become pregnant (and need to consider possible fetal toxicity of regimens). The footnote to Table 10-A is consistent with this recommendation: "See Section 5, Antiretroviral Treatment, for more information on ART, nPEP, and PrEP. HHS does not recommend repeated courses of nPEP (e.g., for discordant couples who rarely use condoms) as a long-term means to prevent HIV acquisition."

6. **Comment**: P. 184. Regarding the passage, "No contraceptive method, including male and female condoms or hormonal contraceptives, is 100% effective in preventing pregnancy, although several methods are more than 99% effective when used correctly with all acts of intercourse," the reviewer advises a recommendation for dual contraception.
   Response: P. 207. Dual contraception recommendations were added to Box 10 and 10-A and covered in the Evidence topic, "Current HHS recommendations conclude that concurrent use of barrier contraception, such as male or female condoms, and nonbarrier contraception, such as hormonal contraception and IUDs, is more effective in preventing pregnancy than using a single contraceptive method and reduces the risk of sexual transmission of HIV."

7. **Comment**: P. 194. Regarding the passage, "Section 4, Linkage to and Retention in Care, and Section 10, Reproductive Health Care, address the importance of immediately linking women of reproductive age with positive preliminary or confirmed HIV test results to HIV and reproductive health care to prevent ongoing sexual transmission, unintended pregnancies, and perinatal transmission," the reviewer suggests mentioning the high unintended pregnancy rate in adolescents with HIV and citing this reference: JAMA 2012, Agwu.

   Response: P. 212**.** The Special Populations topic was revised to read: "Adolescents diagnosed with HIV have high rates of unintended pregnancy and they should receive prompt linkage to HIV medical providers who can provide reproductive health services." The Agwu reference was added.

Comments from Marrazzo

1. **Comment**: P. 178. Regarding the passage, "Most continue sexual activity after their HIV diagnosis, (usually using safer sex practices)," the reviewer indicated that the current epidemic rates of syphilis observed in HIV+ MSM do not support this statement.
   Response: P. 196. This passage was revised as: "Many persons with HIV of reproductive age who know their infection status engage in safer sex practices or use contraception to prevent unintended pregnancy, but some do not."

2. **Comment**: P. 180. Regarding the passage, "Caution that repeated or prolonged use of nPEP while attempting conception through unprotected intercourse is not recommended because information about the safety and efficacy of nPEP regimens when attempting conception and early pregnancy is very limited and other methods allow persons with HIV to conceive without repeated acts of unprotected sexual intercourse," the reviewer suggested emphasizing that this limited use does not refer to PrEP and asks if only clinical providers are relevant.
   Response: P. 198. This educational recommendation was revised to direct it to both nonclinical health educators and clinical providers and to separate issues about nPEP and PrEP: "Inform persons with HIV (and HIV-uninfected partners referred by them) about the availability of PrEP for HIV-uninfected partners when clinically indicated to reduce the risk of HIV acquisition during unprotected sexual intercourse (i.e., penile-vaginal intercourse without using a protective barrier) when attempting conception; and the availability of nPEP for HIV-uninfected partners when clinically indicated on a one-time, nonrepeated basis to reduce the risk of HIV acquisition in the event of inadvertent sexual or parenteral HIV exposure within the past 72 hours (e.g., unprotected intercourse, condom breakage, shared drug-injection equipment)." Additional details distinguish nPEP and PrEP in Box 10 A.

3. **Comment**: P. 190. Regarding the passage, "Evidence-based criteria regarding medical eligibility for contraception for HIV-infected women are detailed elsewhere" the reviewer suggests citing newer systematic reviews (Polis 2013, Phillips 2013).
   Response: P. 207. These reviews were added in the Evidence topic, Family Planning header.

Section 11 – Prevention of HIV Transmission Related to Pregnancy

Comments from Thrun

1. **Comment**: P. 200 (Box 11 A). Regarding the recommendation, "Encourage women to disclose their HIV status to sex and drug-injection partners," the reviewer suggests using a stronger verb such as "assist, develop a plan, etc."
   Response: P. 218. This recommendation was revised as: "Offer women support, information, and assistance to notify their sex and drug-injection partners about their HIV status."

2. **Comment**: P. 200 (text box). Regarding the recommendation, "Encourage voluntary decisions about initiating ART during pregnancy after explaining options to access subsidized ART," the reviewer asks if the recommendation is placed properly and is strong enough. He suggests that such a weak recommendation might encourage some low income HIV+ women (or the health providers who serve them) to defer starting ART.
   Response: P. 218. This recommendation was deleted for the reasons cited by the reviewer.

3. **Comment**: P. 201 (text box). Regarding the recommendation "Notify infant care providers of impending birth of HIV-exposed infant and any anticipated complications," the review asks if providers would include neonatologists, pediatricians, or other medical care providers.

Response: P. 218. This recommendation was revised to clarify it refers to health care providers of any type: "Notify infant health care providers of impending birth of HIV-exposed infant and any anticipated complications."

4. **Comment**: P. 206, (text box). Regarding the passage, "Offer rapid HIV testing to women of unknown HIV status who first present for pregnancy care in labor (using opt-out testing strategy when allowed by jurisdiction) and provide information about perinatal HIV transmission, as feasible," the reviewer advises adding use of HIV antigen or viral load tests that enable detection of acute infection.
   Response: P. 223. This single recommendation was replaced with two recommendations as follows: 1) "Offer expedited HIV testing to women of unknown HIV status who first present for pregnancy care during labor (using opt-out testing strategy when allowed by the jurisdiction) and provide information about perinatal HIV transmission."; and 2) "Conduct repeat testing during the third trimester (using a test that detects recent HIV infection) for women whose earlier HIV test was negative. When a woman has a recent exposure that might cause very recent infection that would not be detected by antibody test alone (i.e., during the window period) or has signs or symptoms consistent with acute HIV infection, use both an HIV antibody test and a plasma RNA test to enable diagnosis of acute HIV infection."

5. **Comment**: P. 214.The reviewer suggests these changes, "Most studies have shown that the risk of HIV transmission to the infant is less than 2% in women who undergo cesarean delivery for obstetric indications after labor and membrane rupture and in women who undergo vaginal delivery ~~among women~~ while taking perinatal ART."
   Response: P. 229. The passage was revised as follows, "Studies have shown that the risk of HIV transmission to the infant is less than 2% in women with varied levels of viral suppression who undergo cesarean delivery for obstetric indications after labor and membrane rupture and in women who have vaginal delivery while taking prenatal ART."

6. **Comment**: P. 217; Regarding the passage, "Providers who explain options to access affordable ART, including subsidized ADAP or commercial drug assistance programs for eligible patients, may speed access to ART and encourage adherence," the reviewer notes this supportive approach is more likely to motivate ART initiation and adherence.
   Response: P. 234. This passage was revised to provide more detail: "Information from providers on how to access safe, affordable ART, including through private insurance, subsidized AIDS Drug Assistance Program (ADAP), or commercial drug assistance programs, and how to manage side effects may help encourage women to initiate regimens that are safe during pregnancy and to achieve high adherence." Also, Box 11-A was revised to add this recommendation: "Inform women about options for free or subsidized ART, such as AIDS Drug Assistance Program (ADAP) or pharmaceutical drug assistance programs to help address financial concerns that may deter ART use."

Section 12 – Services for Other Medical and Social Issues that influence HIV Transmission

Comment from Walensky

1. **Comment**: P. 226. The reviewer advises updating the literature search.
   Response: P. 242. The literature was updated with a few recent references that reinforce existing evidence or extend the Evidence.

2. **Comment**: P. 230. Regarding the following text, "When persons with HIV transition to or from correctional facilities, they risk losing their housing, jobs, transportation, financial resources, health insurance, and services for substance abuse, mental health, or other special needs," the reviewer suggests mentioning access to ART here ?
   Response: P. 245. The passage was revised here and Table 12-1 (service column) to read: "When persons with HIV transition to or from correctional facilities, they may lose access to their source of HIV medical care; access to ART; their housing, jobs, transportation, financial resources, and health insurance; and services for substance abuse, mental health, or other special needs."

3. **Comment**: P. 231. Regarding the passage, "Providers who routinely assess transportation options, offer transportation to prevention services, and advocate for community transportation programs can help persons with HIV overcome this barrier," the reviewer suggests mentioning access to childcare services?
   Response: P. 241. We revised and updated passage with new evidence: "Studies in rural and urban Alabama have shown that HIV clinics that routinely assess childcare and transportation options, offer childcare assistance and transportation to prevention services, and advocate for community programs for these services can help persons engage in HIV care."

4. **Comment**: P. 232. Regarding the passage, "Finally, adolescents with perinatally acquired HIV may now be taking on more responsibility for their adherence than they did as children or younger adolescents," the reviewer advised mentioning that this responsibility increased when patients transition from pediatric to adult clinics.
   Response: P. 248. This passage was revised as:" Providers can also prepare adolescents who are transitioning from pediatric to adult health care providers about differences in patient support services or offer orientation to the new care setting."

5. **Comment**: P. 236. [Referring to "Legal Assistance"] from table 12-1. The reviewer advises adding the service of linkage to and facilitating access to ART and facilitating transitions to and from correctional facilities
   Response: P. 252. The passage was revised as: "Linkage to medical care and ART access for newly incarcerated and soon-to-be released prisoners"

6. **Comment**: P. 237. Table 12-1. The reviewer notes that 'child care' was listed next to "transportation barriers" but was not discussed in the evidence review text.
   Response: P. 253. Child care is now covered in the Evidence topic.

Comment from Del Rio

1. **Comment**: General comment: Recommendations about avoiding discrimination are obvious and unnecessary.
   Response: P. 241. See response to Comment # 3 by Del Rio in Section 3.

Comments from Baker

1. **Comment**: P. 227. The reviewer thought Section 12 was extremely well done, but that the Evidence section does not provide enough information on how each issue contributes to the potential of the person transmitting HIV.
   Response: P. 243. Text and Table 12-1 was revised to provide better explanation of how each issue is associated with transmission risk or access to prevention services.

2. **Comment**: P. 227**.** The reviewer asked if any literature addressed the effects of homophobia and other environmental factors. He advised adding sections on 1) lack of legal protections that address anti-gay laws, and 2) how negative attitudes toward transgender persons and drug users may contribute to conditions and behaviors that increase HIV-related risks (sex work without a condom, not seeking HIV care, etc.)
   Response: P. 243. A literature review was not conducted on this topic, but is briefly noted in topic on "Legal Detention": "Persons with HIV who carry condoms or new, sterile drug-injection equipment in public may be vulnerable to prosecution for commercial sex work or drug use, respectively. Detained or incarcerated persons with HIV may not disclose substance use, sex work, or other illegal activities that caused their infection because of concerns about prosecution, discrimination, or breach of confidentiality."

Comment from Kalichman on ART Adherence section that was addressed here

1. **Comment**: Regarding Section 6 (Adherence), the reviewer suggested adding more information on the role of food insecurity and ART use in the Adherence section.
   Response: P. 243. Food insecurity is noted as an adherence barrier (with citation to the reviewer's work) in Table 12-1, Section 12 because this section was based on a narrative review of studies through 2014, including those that were not identified in the systematic review. Corresponding language was also modified as follows: "Poverty may also lead to unstable housing and insufficient food intake that can impair ART adherence or force people to pay for basic necessities instead of ART medications."

Section 13 – Quality Improvement and Program Monitoring and Evaluation

Comments from Baker

1. **Comment**: P. 246-247; Regarding this text in the Background, "The National Quality Center provides QI resources through its website (http://nationalqualitycenter.org) and no-cost technical assistance for Ryan White HIV/AIDS Program-funded grantees to conduct QI activities," the reviewer noted that the sentence and the Web site language do not make it

clear if these are resources for any provider or just RW grantees and suggests adding resources (including ones for small medical practices) in a side box.
Response: P. 263. This sentence was removed and resources for all provider types are included in the on-line Resource Library noted in the Implementation Resources link.

2. **Comment**: P. 248. Regarding this header text in Box 13-A, "Strategies to support quality improvement in HIV prevention services," the reviewer advised presenting this information in practical action steps that are suited to all settings.
   Response: P. 265. No revisions were made because these strategies apply to most settings. Also, the use of 'strategies' is preferred over 'action steps' because the term more consistent with other boxes and does not imply a specific order.

3. **Comment**: P. 249. Regarding Figure 13-1 (CDC framework for program evaluation), the reviewer questioned if this model was helpful.
   Response: P. 265. Other reviewers value it so the model was retained.

4. **Comment**: P. 250. Regarding Table 13-1 (Example of quality improvement initiative to reduce infectiousness of persons with HIV in an HIV care clinic using the Plan-Do-Study-Act model), the reviewer considered this useful and replicable across a number of settings.
   Response: P. 265. We appreciate this comment.

5. **Comment**: P. 251. Regarding this text, "If QI and M&E results are used to create incentives rather than to highlight individual failures, they are more likely to be acceptable to HIV organizations' culture," the reviewer asked if this is limited to HIV organizations or is it just a general finding about organizations. Presumably, most settings where the care is delivered will not identify as an HIV organization. Throughout the document, I think there should be consideration as to how to make it relevant and accessible to general healthcare practices.
   Response: P. 268. This point applies to all settings.

ADDITIONAL COMMENTS:
Each reviewer was asked to answer the following questions and responses were tallied below. However, some reviewers did not answer a given question. Initials indicate name of reviewer:
Dr. Cornelius Baker: CB
Dr. Carlos del Rio: CR
Dr. Seth Kalichman: SK
Dr. Jeanne Marrazzo: JM
Dr. Mark Thrun: MT
Dr. Rochelle Walensky: RW

FORM A – page 1	**For each question, enter Y (Yes) or N (No). If you entered No, explain in comment field below.**
The following questions relate to Section 2 (Methods) or the Appendix	**Response**
1. Does the Methods Section (Section 2) clearly explain that some recommendations restate existing federal government guidance and some new recommendations are based on evidence, program experience or expert opinion described in the draft?	**3 – Yes; MT, JM, RW**
2. Are the somewhat heterogeneous Methods for developing recommendations appropriate given this broad range of topics?	**1- Yes; JM 1- yes; RW (see additional comments) 1- yes/no, MT (see additional comments)**
3. Is rationale for not grading the quality of evidence or strength of recommendations clear and appropriate?	**2- Yes; JM, MT 1- yes RW (see additional comments)**
4. Would most readers find useful an Appendix that compiles the main recommendations boxes from ALL sections (~20 extra pages if only main recommendation boxes, ~ 40 extra pages if "side boxes" added)	**1- yes JM 2- yes RW, MT (both reviewers: see additional comments)**

Below questions relate to specific sections assigned to you. WRITE IN YOUR SECTION NUMBERS AT TOP OF COLUMN. Question: In this section…										
Question	Sec 3	Sec 4	Sec 5	Sec 6	Sec 7	Sec 8	Sec 9	Sec 10	Sec 11	Sec 12
5. Is the audience for each recommendation clear and appropriate (e.g., clinicians, non-clinical providers, health departments)?	**2-Y (JM,RW) 1-maybe (MT)**	**1 –Y (SK)**	**1 –Y (RW)**	**1-Y (SK)**	**1-Y (SK)**	**2-Y (MT, JM)**	**2-Y (MT, JM)**	**2-Y (RW, JM)**	**2-Y (MT, JM)**	**1 –Y (RW)**
6. Are the Roman number and superscripts used to note the basis for each recommendation clear?	**3- Y (JM,RW,MT)**	**1 –Y (SK)**	**1 –Y (RW)**	**1-Y (SK)**	**1-N (SK)**	**2-Y (MT, JM)**	**2-Y (MT, JM)**	**2-Y (RW, JM)**	**2-Y (MT, JM)**	**1 –Y (RW)**
7. Are methods to develop recommendations appropriate for topic?	**3- Y (JM,RW,MT)**	**1 –Y (SK)**	**1 –Y (RW)**	**1-Y (SK)**	**1-N (SK)**	**2-Y (MT, JM)**	**2-Y (MT, JM)**	**2-Y (RW, JM)**	**2-Y (MT, JM)**	**1 –Y (RW)**
8. Is it clear that the <u>level of obligation</u> for <u>recommended actions</u> (noted in boxes marked *Recommendations* or *Recommended*) is higher than that for <u>optional actions</u> (noted in "side boxes" listing options, strategies, or possible methods)?	**3- Y (JM,RW,MT)**	**1 –Y (SK)**	**1 –Y (RW)**	**1-Y (SK)**	**1-Y (SK)**	**2-Y (MT, JM)**	**2-Y (MT, JM)**	**2-Y (RW, JM)**	**2-Y (MT, JM)**	**1 –Y (RW)**
9. Are recommendations that <u>restate existing federal guidance</u> (noted by Roman numbers) accurate & relevant for section's scope?	**3-Y (JM,RW,MT)**	**1 –Y (SK)**	**1 –Y (RW)**	**1-Y (SK)**	**1-N (SK)**	**1-N (JM) 1-Y (MT)**	**1-N (JM) 1-Y (MT)**	**2-Y (RW, JM)**	**2-Y (MT, JM)**	**1 –Y (RW)**
10. Is the evidence or expert opinion supporting <u>new recommendations</u> complete, clear and appropriately interpreted?	**3- Y (JM,RW,MT)**	**1 –Y (SK)**	**1 –Y (RW)**	**1-Y (SK)**	**1-N (SK)**	**2-Y (MT, JM)**	**1-N (JM) 1-Y (MT)**	**1-N (JM) 1 –Y (RW)**	**2-Y (MT, JM)**	**1 –Y (RW)**
11. Are the most important <u>limitations of this evidence</u>	**3- Y**	**1 –Y**	**1 –Y**	**1-Y**	**1-N**	**1-N**	**1-N**	**2-Y**	**2-Y**	**1 –Y**

adequately described?	**(JM,RW,MT)**	**(SK)**	**(RW)**	**(SK)**	**(SK)**	**(JM) 1-Y (MT)**	**(JM) 1-Y (MT)**	**(RW, JM)**	**(MT, JM)**	**(RW)**
12. Are new recommendations based on evidence, program experience or expert opinion appropriate and clear?	**3- Y (JM,RW,MT)**	**1 –Y (SK)**	**1 –Y (RW)**	**1-Y (SK)**	**1-N (SK)**	**1-N (JM) 1-Y (MT)**	**1-N (JM) 1-Y (MT)**	**2-Y (RW, JM)**	**2-Y (MT, JM)**	**1 –Y (RW)**
13. Are statements in "side boxes" appropriate and clear given statements in recommendation boxes?	**3- Y (JM,RW,MT)**	**1 –Y (SK)**	**1 –Y (RW)**	**1-Y (SK)**	**1-N (SK)**	**2-Y (MT, JM)**	**1-N (JM) 1-Y (MT)**	**2-Y (RW, JM)**	**2-Y (MT, JM)**	**1 –Y (RW)**
14. Is it clear how these recommendations differ from and/or are consistent with past federal recommendations on this section topic?	**3- Y (JM,RW,MT)**	**1 –Y (SK)**	**1 –Y (RW)**	**1-Y (SK)**	**1-N (SK)**	**2-Y (MT, JM)**	**2-Y (MT, JM)**	**2-Y (RW, JM)**	**2-Y (MT, JM)**	**1 –Y (RW)**
15. Are descriptions of the benefits and limitations of the recommendations appropriate and clear?	**3- Y (JM,RW,MT)**	**1 –Y (SK)**	**1 –Y (RW)**	**1-Y (SK)**	**1-N (SK)**	**2-Y (MT, JM)**	**1-N (JM) 1-Y (MT)**	**2-Y (RW, JM)**	**2-Y (MT, JM)**	**1 –Y (RW)**